DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

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DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9940–F2]

RIN 0938–AT54

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, interim final rules concerning religious exemptions and accommodations regarding coverage of certain preventive services issued in the **Federal Register** on October 13, 2017. These rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an "accommodation" process as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT: Jeff Wu, at (301) 492–4305 or *marketreform@cms.hhs.gov* for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS); Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; William Fischer, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline, 1–866–444–EBSA (3272) or visit the Department of Labor's website (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of this rule is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47792). "Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" (the Religious IFC). The rules are necessary to expand the protections for the sincerely held religious objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their exercise of religious beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, a requirement that was created by HHS through guidance promulgated by the Health Resources and Services Administration (HRSA) (hereinafter "Guidelines"), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules maintain a previously created accommodation process that permits entities with certain religious objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their health insurance issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's Guidelines. The changes being finalized to these rules will ensure that proper respect is afforded to sincerely held religious objections in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Expanded Religious Exemptions to the Contraceptive Coverage Requirement

These rules finalize exemptions provided in the Religious IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held religious beliefs opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's Guidelines. The rules finalize exemptions to the same types of organizatons and individuals for which exemptions were provided in the Religious IFC: Non-governmental plan sponsors including a church, an integrated auxiliary of a church, a convention or association of churches, or a religious order; a nonprofit organization; for-profit entities; an institution of higher education in arranging student health insurance coverage; and, in certain circumstances, issuers and individuals. The rules also finalize the regulatory restatement in the Religious IFC of language from section 2713(a) and (a)(4) of the Public Health Service Act.

In response to public comments, various changes are made to clarify the intended scope of the language in the Religious IFC. The prefatory language to the exemptions is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to clarify that, where an exemption encompasses a plan or coverage established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, the exemption applies to each employer, organization, or plan sponsor that adopts the plan. Language is also added to clarify that the exemptions apply to non-governmental entities, including as the exemptions apply to institutions of higher education. The Departments revise the exemption applicable to health insurance issuers to make clear that the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement. The Departments also restructure the provision describing the religious objection for entities. That provision specifies that the entity objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for either: coverage or payments for some or all contraceptive services; or, a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The final rule specifies that the individual exemption ensures that the HRSA Guidelines do not prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. Optional Accommodation

These rules also finalize provisions from the Religious IFC that maintain the accommodation process as an optional process for entities that qualify for the exemption. Under that process, entities can choose to use the accommodation process so that contraceptive coverage to which they object is omitted from their plan, but their issuer or third party administrator, as applicable, will arrange for the persons covered by their plan to receive contraceptive coverage or payments.

In response to public comments, these final rules make technical changes to the accommodation regulations maintained in parallel by HHS, the Department of Labor, and the Department of the Treasury. The Departments modify the regulations governing when an entity, that was using or will use the accommodation, can revoke the accommodation and operate under the exemption. The modifications set forth a transitional

rule as to when entities currently using the accommodation may revoke it and use the exemption by giving 60-days notice pursuant to Public Health Service Act section 2715(d)(4) and 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), and 29 CFR 2590.715–2715(b). The modifications also express a general rule that, in plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an organization eligible for the accommodation may revoke its use of the accommodation process effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

The Departments also modify the Religious IFC by adding a provision that existed in rules prior to the Religious IFC, namely, that if an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable contraceptive coverage requirement from HRSA's Guidelines if the issuer complies with the obligations under this section applicable to such issuer. Likewise, the rule adds pre-existing "reliance" language deeming an issuer serving an accommodated organization compliant with the contraceptive coverage requirement if the issuer relies reasonably and in good faith on a representation by an organization as to its eligibility for the accommodation and the issuer otherwise complies with the accommodation regulation, and likewise deeming a group health plan compliant with the contraceptive coverage requirement if it complies with the accommodation regulation.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and benefits	Costs
Restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	The purpose of this provision is to ensure that the regulatory language that restates section 2713(a) and (a)(4) of the Public Health Service Act mirrors the language of the statute. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.
Expanded religious exemptions.	Expanding religious exemptions to the contraceptive coverage requirement will relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their religious beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage or using the accommodation in violation of their sincerely held religious beliefs.	We estimate there will be transfer costs where women previously receiving contraceptive coverage from employers will no longer receive that coverage where the employers use the expanded exemptions. Even after the public comment period, we have very limited data on what the scale of those transfer costs will be. We estimate that in no event will they be more than $68.9 million. We estimate that, where entities using the accommodation revoke it to use the exemption, the cost to industry of sending notices of revocation to their policy holders will be $112,163.
Optional accommodation regulations.	Maintaining the accommodation as an optional process will ensure that contraceptive coverage is made available to many women covered by plans of employers that object to contraceptive coverage but not to their issuers or third party administrators arranging for such coverage to be provided to their plan participants.	We estimate that, by expanding the types of organizations that may use the accommodation, some entities not currently using it will opt into it. When doing so they will incur costs of $677 to send a self-certification or notice to their issuer or third party administrator, or to HHS, to commence operation of the accommodation. We estimate that entities that newly make use of the accommodation as the result of these rules, or their issuers or third party administrators, will incur costs of $311,304 in providing their policy holders with notices indicating that contraceptive coverage or payments are available to them under the accommodation process.

B. Background

Over many decades, Congress has protected conscientious objections, including those based on religious beliefs, in the context of health care and human services including health coverage, even as it has sought to promote and expand access to health services.[1] In 2010, Congress enacted the

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their "religious beliefs or moral convictions"); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any "health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion for any reason); *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions"); *id.* at Div. E, Sec. 808 (regarding any requirement for "the provision of contraceptive coverage by health insurance plans" in the District of Columbia, "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions."); *id.* at Div. I, (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their "religious or conscientious commitment to offer only natural family planning"); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide-related treatment services for youth where the parents or legal guardians object based on "religious beliefs or moral objections"); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations

Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended the PPACA. As amended by HCERA, the PPACA is known as the Affordable Care Act (ACA).

The ACA reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter "section 2713(a)(4)"), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women's preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, "with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by" HRSA's Guidelines.

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.[2] In the same time period, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, "the Departments")[3] have promulgated regulations to guide HRSA in exercising its discretion to allow exemptions to those requirements, including issuing and finalizing three interim final regulations prior to 2017.[4] In those regulations, the Departments defined the scope of permissible exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Many individuals and entities brought legal challenges to the contraceptive coverage requirement and regulations (hereinafter, the "contraceptive Mandate," or the "Mandate") as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1 ("RFRA"). Several of those cases went to the Supreme Court. *See, for example, Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014); *Zubik* v. *Burwell*, 136 S. Ct. 1557 (2016).

The Departments most recently solicited public comments on these issues again in two interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017: the regulations (82 FR 47792) that are being finalized with changes here, and regulations (82 FR 47838) concerning moral objections (the Moral IFC), which are being finalized with changes in companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Religious IFC, the Departments explained several reasons why it was appropriate to reevaluate the religious exemptions and accommodations for the contraceptive Mandate and to take into account the religious beliefs of certain employers concerning that Mandate. The Departments also sought public comment on those modifications. The Departments considered, among other things, Congress's history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; protection of the free exercise of religion in the First Amendment and, by Congress, in RFRA; Executive Order 13798, "Promoting Free Speech and Religious Liberty" (May 4, 2017); previously submitted public comments;

and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice (now Medicare Advantage) managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on "conscience" as protected in state law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on "religious beliefs or moral convictions"); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); see also 8 U.S.C. 1182(g) (protecting vaccination objections by "aliens" due to "religious beliefs or moral convictions"); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on "moral or religious convictions"); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their "religious or moral objection").

[2] The references in this document to "contraception," "contraceptive," "contraceptive coverage," or "contraceptive services" generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women's Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to "Contraceptive Methods and Counseling" as "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." *https://www.hrsa.gov/womens-guidelines/index.html.* The Guidelines as amended in December 2016 refer, under the header "Contraception," to: "the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures," "contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method)," and "instruction in fertility awareness-based methods, including the lactation amenorrhea method." *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[3] Note, however, that in sections under headings listing only two of the three Departments, the term "Departments" generally refers only to the two Departments listed in the heading.

[4] Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

and the extensive litigation over the contraceptive Mandate.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Religious IFC, with changes based on comments as indicated herein.[5]

II. Overview, Analysis, and Response to Public Comments

We provided a 60-day public comment period for the Religious IFC, which closed on December 5, 2017. The Departments received over 56,000 public comment submissions, which are posted at *www.regulations.gov*.[6] Below, the Departments provide an overview of the general comments on the final regulations, and address the issues raised by commenters.

These rules expand exemptions to protect religious beliefs for certain entities and individuals with religious objections to contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules finalize the accommodation process, which was previously established in response to objections of religious organizations that were not protected by the original exemption, as an optional process for any exempt entities. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.[7]

A. The Departments' Authority To Mandate Coverage and Provide Religious Exemptions

The Departments received conflicting comments on their legal authority to provide the expanded exemptions and accommodation for religious beliefs. Some commenters agreed that the Departments are legally authorized to provide the expanded exemptions and accommodation, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing religious exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the exemptions that existed prior to the Religious IFC, but not to expand them.

Some commenters who argued that section 2713(a)(4) does not allow for exemptions said that the previous exemptions for houses of worship and integrated auxiliaries, and the previous accommodation process, were set forth in the ACA itself, and therefore were acceptable while the expanded exemptions in the Religious IFC were not. This is incorrect. The ACA does not prescribe (or prohibit) the previous exemptions for house of worship and the accommodation processes that the Departments issued through regulations.[8] The Departments, therefore, find it appropriate to use the regulatory process to issue these expanded exemptions and accommodation, to better address concerns about religious exercise.

The Departments conclude that legal authority exists to provide the expanded exemptions and accommodation for religious beliefs set forth in these final rules. These rules concern section 2713 of the PHS Act, as also incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes.[9]

Where it applies, section 2713(a)(4) requires coverage without cost sharing for "such additional" women's preventive care and screenings "as provided for" and "supported by" Guidelines developed by HHS through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS, as the administering agency of HRSA, and to all three agencies, as the administering agencies of the statutes by which the Guidelines are enforced, to shape that development. *See* 26 U.S.C. 9834; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38,409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable Guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must "provide for" and "support" the application of Guidelines that it chooses to adopt. HRSA's authority to support "comprehensive guidelines" involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only "as provided for in comprehensive guidelines supported by [HRSA]." That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word "as" in the phrase "as provided for," it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase "as you like it."[10] When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See, e.g.*, 42 U.S.C. 1395x ("The Secretary shall establish procedures to make beneficiaries and providers aware

[5] The Department of the Treasury and the Internal Revenue Service (IRS) published proposed and temporary regulations as part of the joint rulemaking of the Religious IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules. The Department of the Treasury and IRS are finalizing their proposed regulations.

[6] *See Regulations.gov* at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dktid=CMS-2014-0115* and *https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=7525&dct=PS&D=IRS-2017-0016*. Some of those submissions included form letters or attachments that, while not separately tabulated at *regulations.gov*, together included comments from, or were signed by, hundreds of thousands of separate persons. The Departments reviewed all of the public comments and attachments.

[7] *See, for example*, Family Planning grants in 42 U.S.C. 300 *et seq.*; the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.*; the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), and 25 U.S.C. 1601, *et seq.*; Health center grants, 42 U.S.C. 254b(e), (g), (h), and (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[8] The ACA also does not require that contraceptives be covered under the preventive services provisions.

[9] 26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92.

[10] See As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) ("[u]sed to indicate by comparison the way something happens or is done").

of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.") (emphasis added). Thus, the inclusion of "as" in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has been granted discretion in supporting how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word "as" is missing from the other three provisions in PHS Act section 2713(a). Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require "evidence-based" or "evidence-informed" coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The religious objections at issue here, and in regulations providing exemptions from the inception of the Mandate in 2011, are considerations that, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines "exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women," and "it is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans." *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a specific statutory mandate that contraceptives must be covered or that they be covered without any exemptions or exceptions, supports the conclusion that the Departments are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The conclusions on which these final rules are based are consistent with the Departments' interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4)'s grant of authority to include broad discretion regarding the extent to which HRSA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments defined the scope of the exemption to the contraceptive Mandate when HRSA issued its Guidelines for contraceptive coverage in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrators of self-insured church plans. *See* 80 FR 41323. Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. During prior rulemakings, the Departments also disagreed with commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or as incorporated into ERISA and the Code, and who contended instead that we must enforce the Guidelines on the broadest spectrum of group health plans as possible. *See, e.g.,* 2012 final regulations at 77 FR 8726.

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require coverage of preventive services for every type of plan that is subject to the ACA. *See, e.g.,* 76 FR 46623. On the contrary, Congress carved out an exemption from PHS Act section 2713 (and from several other provisions) for grandfathered plans. In contrast, grandfathered plans do have to comply with many of the other provisions in Title I of the ACA—provisions referred to by the previous Administration as providing "particularly significant protections." (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime and annual dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group health insurance markets, and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.[11] Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." *Hobby Lobby,* 134 S. Ct. at 2764 n.10.

Some commenters argue that Executive Order 13535's reference to

[11] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," Henry J Kaiser Family Foundation (Sept. 2017), *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions to the Mandate in the Guidelines. The Departments, however, believe these final regulations are consistent with Executive Order 13535. Issued upon the signing of the ACA, Executive Order 13535 specified that ''longstanding Federal laws to protect conscience . . . remain intact,'' including laws that protect holders of religious beliefs from certain requirements in health care contexts. While the Executive Order 13535 does not require the expanded exemptions in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws that protect religious beliefs, and are consistent with the Executive Order's intent that the ACA would be implemented in accordance with the conscience protections set forth in those laws.

The extent to which RFRA provides authority for these final rules is discussed below in section II.C., The First Amendment and the Religious Freedom Restoration Act.

B. Availability and Scope of Religious Exemptions

Some commenters supported the expanded exemptions and accommodation in the Religious IFC, and the entities and individuals to which they applied. They asserted the expanded exemptions and accommodation are appropriate exercises of discretion and are consistent with religious exemptions Congress has provided in many similar contexts. Some further commented that the expanded exemptions are necessary under the First Amendment or RFRA. Similarly, commenters stated that the accommodation was an inadequate means to resolve religious objections, and that the expanded exemptions are needed. They objected to the accommodation process because it was another method to require compliance with the Mandate. They contended its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and that such coverage flowed in connection with the objecting organizations' health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to the religious objections that organizations would not have with an expanded exemption.

Several other commenters asserted that the exemptions in the Religious IFC are too narrow and called for there to be no mandate of contraceptive coverage. Some of them contended that HRSA should not include contraceptives in their women's preventive services Guidelines because fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of preventive health services. They also contended that contraceptives can pose medical risks for women and that studies do not show that contraceptive programs reduce abortion rates or rates of unintended pregnancies. Some commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacients and, therefore, violate federal conscience protections such as the Weldon Amendment. *see* section 507(d) of Public Law 115–141.

Other commenters contended that the expanded exemptions are too broad. In general, these commenters supported the inclusion of contraceptives in the Guidelines, contending they are a necessary preventive service for women. Some said that the Departments should not exempt various kinds of entities such as businesses, health insurance issuers, or other plan sponsors that are not nonprofit entities. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318). Some commenters said the Departments should not expand the exemptions, but simply expand or adjust the accommodation process to resolve religious objections to the Mandate and accommodation. Some commenters contended that even the previous regulations allowing an exemption and accommodation were too broad, and said that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible.

After consideration of the comments, the Departments are finalizing the provisions of the Religious IFC without contracting the scope of the exemptions and accommodation set forth in the Religious IFC. Since HRSA issued its Guidelines in 2011, the Departments have recognized that religious exemptions from the contraceptive Mandate are appropriate. The details of the scope of such exemptions are discussed in further detail below. In general, the Departments conclude it is appropriate to maintain the exemptions created by the Religious IFC to avoid instances where the Mandate is applied in a way that violates the religious beliefs of certain plan sponsors, issuers, or individuals. The Departments do not believe the previous exemptions are adequate, because some religious objections by plan sponsors and individuals were favored with exemptions, some were not subjected to contraceptive coverage if they fell under the indirect exemption for certain self-insured church plans, and others had to choose between the Mandate and the accommodation even though they objected to both. The Departments wish to avoid inconsistency in respecting religious objections in connection with the provision of contraceptive coverage. The lack of a congressional mandate that contraceptives be covered, much less that they be covered without religious exemptions, has also informed the Departments' decision to expand the exemptions. And Congress's decision not to apply PHS Act section 2713 to grandfathered plans has likewise informed the Departments' decision whether exemptions to the contraceptive Mandate are appropriate.

Congress has also established a background rule against substantially burdening sincere religious beliefs except where consistent with the stringent requirements of the Religious Freedom Restoration Act. And Congress has consistently provided additional, specific exemptions for religious beliefs in statutes addressing federal requirements in the context of health care and specifically concerning issues such as abortion, sterilization, and contraception. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive coverage Mandate by the exercise of agency discretion, that we also include exemptions for the protection of religious beliefs in certain cases. The expanded exemptions finalized in these rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. They are also consistent with the intent of Executive Order 13535 (March 24, 2010), which was issued upon the signing of the ACA and declared that, ''[u]nder the Act, longstanding federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Public Law 111–8) remain intact'' and that ''[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS.''

Some commenters argued that Congress's failure to explicitly include

religious exemptions in PHS Act section 2713 itself is indicative of an intent that such exemptions not be included, but the Departments disagree. As noted above, Congress also failed to require contraceptive coverage in PHS Act section 2713. And the commenters' argument would negate not just these expanded exemptions, but the previous exemptions for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting religious beliefs in the context of certain federal health care requirements.

If there is to be a federal contraceptive mandate that fails to include some—or, in the views of some commenters, any—religious exemptions, the Departments do not believe it is appropriate for us to impose such a regime through discretionary administrative measures. Instead, such a serious imposition on religious liberty should be created, if at all, by Congress, in response to citizens exercising their rights of political participation. Congress did not prohibit religious exemptions under this Mandate. It did not even require contraceptive coverage under the ACA. It left the ACA subject to RFRA, and it specified that additional women's preventive services will only be required coverage as provided for in Guidelines supported by HRSA. Moreover, Congress legislated in the context of the political consensus on conscientious exemptions for health care that has long been in place. Since *Roe* v. *Wade* in 1973, Congress and the states have consistently offered religious exemptions for health care providers and others concerning issues such as sterilization and abortion, which implicate deep disagreements on scientific, ethical, and religious (and moral) concerns. Indeed over the last 44 years, Congress has repeatedly expanded religious exemptions in similar cases, including to contraceptive coverage. Congress did not purport to deviate from that approach in the ACA. Thus, we conclude it is appropriate to specify in these final rules, that, if the Guidelines continue to maintain a contraceptive coverage requirement, the expanded exemptions will apply to those Guidelines and their enforcement.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for religious beliefs in the context of certain Federal health care requirements. Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held religious beliefs to the extent the Guidelines otherwise include contraceptive coverage.[12] These exemptions do not prohibit any services, nor do they authorize employers to prohibit employees from obtaining any services. The Religious IFC and these final rules simply refrain from imposing the federal Mandate that employers and health insurance issuers cover contraceptives in their health plans where compliance with the Mandate would violate their sincerely held religious beliefs. And though not necessary to the Departments' decision here, the Departments note that the Church Amendments explicitly protect entities and that several subsequent federal conscience statutes have protected against federal mandates in health coverage.

The Departments note that their decision is also consistent with state practice. A significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[13] Although the practice of states is not a limit on the discretion delegated to HRSA by the ACA, nor is it a statement about what the federal government may do consistent with RFRA or other limitations or protections embodied in federal law, such state practices can inform the Departments' view that it is appropriate to protect religious liberty as an exercise of agency discretion.

The Departments decline to adopt the suggestion of some commenters to use these final rules to revoke the contraceptive Mandate altogether, such as by declaring that HHS through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). Although previous regulations were used to authorize religious exemptions and accommodations to the imposition of the Guidelines' coverage of contraception, the issuance of the Guidelines themselves in 2011 describing what items constitute recommended women's preventive services, and the update to those recommendations in December 2016, did not occur through the regulations that preceded the 2017 Religious IFC and these final rules. The Guidelines' specification of which women's preventive services were recommended were issued, not by regulation, but directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The Departments decline to accept the invitation of some commenters to use these rules to specify whether HRSA includes contraceptives in the Guidelines at all. Instead the Departments conclude it is appropriate for these rules to continue to focus on restating the statutory language of PHS Act section 2713 in regulatory form, and delineating what exemptions and accommodations apply if HRSA lists contraceptives in its Guidelines. Some commenters said that if contraceptives are not removed from the Guidelines entirely, some entities or individuals with religious objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in the Religious IFC and these final rules cover a broad range of entities and individuals. The Departments are not aware of specific groups or individuals whose religious beliefs would still be substantially burdened by the Mandate after the issuance of these final rules.

Some commenters asserted that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions.

[12] The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

[13] *See* Guttmacher Institute, "Insurance Coverage of Contraceptives", The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These rules focus on what religious exemptions and accommodations shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacients.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content of, and the process for developing and updating, the Guidelines, are welcome to communicate their views to HRSA, at *wellwomancare@hrsa.gov*.

The Departments conclude that it would be inadequate to merely attempt to amend or expand the accommodation process instead of expanding the exemption. In the past, the Departments had stated in our regulations and court briefs that the previous accommodation process required contraceptive coverage or payments in a way that is "seamless" with the coverage provided by the objecting employer. As a result, in significant respects, that previous accommodation process did not actually accommodate the objections of many entities, as many entities with religious objections have argued. The Departments have attempted to identify an accommodation process that would eliminate the religious objections of all plaintiffs, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but we stated in January 2017 that we were unable to develop such an approach at that time.[14] The Departments continue to believe that, because of the nature of the accommodation process, merely amending that accommodation process without expanding the exemptions would not adequately address religious objections to compliance with the Mandate. Instead, we conclude that the most appropriate approach to resolve these concerns is to expand the exemptions as set forth in the Religious IFC and these final rules, while maintaining the accommodation as an option for providing contraceptive coverage, without forcing entities to choose between compliance with either the Mandate or the accommodation and their religious beliefs.

Comments considering the appropriateness of exempting certain specific kinds of entities or individuals are discussed in more detail below.

C. The First Amendment and the Religious Freedom Restoration Act

Some commenters said that the Supreme Court ruled that the exemptions to the contraceptive Mandate, which the Departments previously provided to houses of worship and integrated auxiliaries, were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but exemptions beyond those are not. But in *Hobby Lobby* and *Zubik*, the Supreme Court did not decide whether the exemptions previously provided to houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate to other organizations unless RFRA prohibits the Departments from doing so. Moreover, the previous church exemption, which applied automatically to all churches whether or not they had even asserted a religious objection to contraception, 45 CFR 147.141(a), is not tailored to any plausible free-exercise concerns. The Departments decline to adopt the view that RFRA does not apply to other religious organizations, and there is no logical explanation for how RFRA could require the church exemption but not this expanded religious exemption, given that the accommodation is no less an available alternative for the former than the latter.

Commenters disagreed about the scope of RFRA's protection in this context. Some commenters said that the expanded exemptions and accommodation are consistent with RFRA. Some also said that they are required by RFRA, as the Mandate imposes substantial burdens on religious exercise and fails to satisfy the compelling-interest and least-restrictive-means tests imposed by RFRA. Other commenters, however, contended that the expanded exemptions and accommodation are neither required by, nor consistent with, RFRA. In this vein, some argued that the Departments have a compelling interest to deny religious exemptions, that there is no less restrictive means to achieve its goals, or that the Mandate or its accommodation process do not impose a substantial burden on religious exercise.

For the reasons discussed below, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement, or to merely attempt to create an accommodation that would mitigate the burden. Here, after further consideration of these issues and review of the public comments, the Departments have determined that a broader exemption, rather than a mere accommodation, is the appropriate response.

In addition, with respect to religious employers, the Departments conclude that, without finalizing the expanded exemptions, and therefore requiring certain religiously objecting entities to choose between the Mandate, the accommodation, or penalties for noncompliance—or requiring objecting individuals to choose between purchasing insurance with coverage to which they object or going without insurance—the Departments would violate their rights under RFRA.

1. Discretion To Provide Religious Exemptions

In the Religious IFC, we explained that even if RFRA does not compel the Departments to provide the religious exemptions set forth in the IFC, the Departments believe the exemptions are the most appropriate administrative response to the religious objections that have been raised.

The Departments received conflicting comments on this issue. Some commenters agreed that the Departments have administrative discretion to address the religious objections even if the Mandate and accommodation did not violate RFRA. Other commenters expressed the view that RFRA does not provide such discretion, but only allows exemptions when RFRA requires exemptions. They contended that RFRA does not require exemptions for entities covered by the expanded exemptions of the Religious IFC, but that subjecting those entities to the accommodation satisfies RFRA, and therefore RFRA provides the Departments with no additional authority to exempt those entities. Those commenters further contended that because, in their view, section 2713(a)(4) does not authorize the

[14] *See* Departments of Labor, Health and Human Services, and the Treasury, "FAQs About Affordable Care Act Implementation Part 36," (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* ("the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage").

expanded exemptions, no statutory authority exists for the Departments to finalize the expanded exemptions.

As discussed above, the Departments disagree with the suggestions of commenters that section 2713(a)(4) does not authorize the Departments to adopt the expanded exemptions. Nevertheless, the Departments note that the expanded exemptions for religious objectors also rest on an additional, independent ground: The Departments have determined that, in light of RFRA, an expanded exemption rather than the existing accommodation is the most appropriate administrative response to the substantial burden identified by the Supreme Court in *Hobby Lobby*. Indeed, with respect to at least some objecting entities, an expanded exemption, as opposed to the existing accommodation, is required by RFRA. The Departments disagree with commenters who contend RFRA does not give the Departments discretion to offer these expanded exemptions.

The Departments' determination about their authority under RFRA rests in part on the Departments' reassessment of the interests served by the application of the Mandate in this specific context. Although the Departments previously took the position that the application of the Mandate to objecting employers was narrowly tailored to serve a compelling governmental interest, as discussed below the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Particularly under those circumstances, the Departments believe that agencies charged with administering a statute that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining whether the appropriate response is to provide an exemption from the burdensome requirement or instead to attempt to create an accommodation that would mitigate the burden. And here, the Departments have determined that a broader exemption rather than the existing accommodation is the appropriate response. That determination is informed by the Departments' reassessment of the relevant interests, as well as by their desire to bring to a close the more than five years of litigation over RFRA challenges to the Mandate.

Although RFRA prohibits the government from substantially burdening a person's religious exercise where doing so is not the least restrictive means of furthering a compelling interest—as is the case with the contraceptive Mandate, pursuant to *Hobby Lobby*—neither RFRA nor the ACA *prescribes* the remedy by which the government must eliminate that burden, where any means of doing so will require departing from the ACA to some extent (on the view of some commenters, with which the Departments disagree, that section 2713(a)(4) does not itself authorize the Departments to recognize exceptions). The prior administration *chose* to do so through the complex accommodation it created, but nothing in RFRA or the ACA compelled that novel choice or prohibits the current administration from employing the more straightforward choice of an exemption—much like the existing and unchallenged exemption for churches. After all, on the theory that section 2713(a)(4) allows for no exemptions, the accommodation also departed from section 2713(a)(4) in the sense that employers were not themselves offering contraceptive coverage, and the ACA did not require the Departments to choose that departure rather than the expanded exemptions as the exclusive method to satisfy their obligations under RFRA to eliminate the substantial burden imposed by the Mandate. The agencies' choice to adopt an exemption in addition to the accommodation is particularly reasonable given the existing legal uncertainty as to whether the accommodation itself violates RFRA. *See* 82 FR at 47798; *see also Ricci* v. *DeStefano,* 557 U.S. 586, 585 (2009) (holding that an employer need only have a strong basis to believe that an employment practice violates Title VII's disparate impact ban in order to take certain types of remedial action that would otherwise violate Title VII's disparate-treatment ban). Indeed, if the Departments had simply adopted an expanded exemption from the outset—as they did for churches—no one could reasonably have argued that doing so was improper because they should have invented the accommodation instead. Neither RFRA nor the ACA compels a different result now based merely on path dependence.

Although the foregoing analysis is independently sufficient, additional support for this view is provided by the Departments' conclusion, as explained more fully below, that an expanded exemption is required by RFRA for at least some objectors. In the Religious IFC, the Departments reaffirmed their conclusion that there is not a way to satisfy all religious objections by amending the accommodation, (82 FR at 47800), a conclusion that was confirmed by some commenters (and the continued litigation over the accommodation).[15] Some commenters agreed the religious objections could not be satisfied by amending the accommodation without expanding the exemptions, because if the accommodation requires an objecting entity's issuer or third party administrator to provide or arrange contraceptive coverage for persons covered by the plan because they are covered by the plan, this implicates the objection of entities to the coverage being provided through their own plan, issuer, or third party administrator. Other commenters contended the accommodation could be modified to satisfy RFRA concerns without extending exemptions to objecting entities, but they did not propose a method of modifying the accommodation that would, in the view of the Departments, actually address the religious objections to the accommodation.

In the Departments' view, after considering all the comments and the preceding years of contention over this issue, it is appropriate to finalize the expanded exemptions rather than merely attempt to change the accommodation to satisfy religious objections. This is because if the accommodation still delivers contraceptive coverage through use of the objecting employer's plan, issuer, or third party administrator, it does not address the religious objections. If the accommodation could deliver contraceptive coverage independent and separate from the objecting employer's plan, issuer, and third party administrator, it could possibly address the religious objections, but there are two problems with such an approach. First, it would effectively be an exemption, not the accommodation as it has existed, so it would not be a reason not to offer the expanded exemptions finalized in these rules. Second, although (as explained above) the Departments have authority to provide exemptions to the Mandate, the Departments are not aware of the authority, or of a practical mechanism, for using section 2713(a)(4) to require contraceptive coverage be provided

[15] *See* RFI, 81 FR 47741 (July 26, 2016); Departments of Labor, Health and Human Services, and the Treasury, "FAQs, About Affordable Care Act Implementation Part 36," (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* ("the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage").

specifically to persons covered by an objecting employer, other than by using the employer's plan, issuer, or third party administrator, which would likely violate some entities' religious objections. The Departments are aware of ways in which certain persons covered by an objecting employer might obtain contraceptive coverage through other governmental programs or requirements, instead of through objecting employers' plans, issuers, or third party administrators, and we mention those elsewhere in this rule. But those approaches do not involve the accommodation, they involve the expanded exemptions, plus the access to contraceptives through separate means.

2. Requiring Entities To Choose Between Compliance With the Contraceptive Mandate or the Accommodation Violated RFRA in Many Instances

Before the Religious IFC, the Departments had previously contended that the Mandate did not impose a substantial burden on entities and individuals under RFRA; that it was supported by a compelling government interest; and that it was, in combination with the accommodation, the least restrictive means of advancing that interest. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with sincerely held religious objections, that argument was rejected in *Hobby Lobby*, which held that the Mandate imposes a substantial burden and was not the least restrictive means of achieving any compelling governmental interest. *See* 134 S. Ct. at 2775–79. In the Religious IFC, the Departments revisited its earlier conclusions and reached a different view, concluding that requiring compliance through the Mandate or accommodation constituted a substantial burden on the religious exercise of many entities or individuals with religious objections, did not serve a compelling interest, and was not the least restrictive means of serving a compelling interest, so that requiring such compliance led to the violation of RFRA in many instances. (82 FR at 47806).

In general, commenters disagreed about this issue. Some commenters agreed with the Departments, and with some courts, that requiring entities to choose between the contraceptive Mandate and its accommodation violated their rights under RFRA, because it imposed a substantial burden on their religious exercise, did not advance a compelling government interest, and was not the least restrictive means of achieving such an interest. Other commenters contended that requiring compliance either with the Mandate or the accommodation did not violate RFRA, agreeing with some courts that have concluded the accommodation does not substantially burden the religious exercise of organizations since, in their view, it does not require organizations to facilitate contraceptive coverage except by submitting a self-certification form or notice, and requiring compliance was the least restrictive means of advancing the compelling interest of providing contraceptive access to women covered by objecting entities' plans.

The Departments have examined further, including in light of public comments, the issue of whether requiring compliance with the combination of the contraceptive Mandate and the accommodation process imposes a substantial burden on entities that object to both, and is the least restrictive means of advancing a compelling government interest. The Departments now reaffirm the conclusion set forth in the Religious IFC, that requiring certain religiously objecting entities or individuals to choose between the Mandate, the accommodation, or incurring penalties for noncompliance imposes a substantial burden on religious exercise under RFRA.

a. Substantial Burden

The Departments concur with the description of substantial burdens expressed recently by the Department of Justice:

> A governmental action substantially burdens an exercise of religion under RFRA if it bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice.
>
> Because the government cannot second-guess the reasonableness of a religious belief or the adherent's assessment of the connection between the government mandate and the underlying religious belief, the substantial burden test focuses on the extent of governmental compulsion involved. In general, a government action that bans an aspect of an adherent's religious observance or practice, compels an act inconsistent with that observance or practice, or substantially pressures the adherent to modify such observance or practice, will qualify as a substantial burden on the exercise of religion.[16]

The Mandate and accommodation under the previous regulation forced certain non-exempt religious entities to choose between complying with the Mandate, complying with the accommodation, or facing significant penalties. Various entities sincerely contended, in litigation or in public comments, that complying with either the Mandate or the accommodation was inconsistent with their religious observance or practice. The Departments have concluded that withholding an exemption from those entities has imposed a substantial burden on their exercise of religion, either by compelling an act inconsistent with that observance or practice, or by substantially pressuring the adherents to modify such observance or practice. To this extent, the Departments believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing substantial burden, to the burdens that an entity faces when it opposes, on the basis of its religious beliefs, complying with the Mandate or participating in the accommodation process, and is subject to penalties or disadvantages that would have applied in this context if it chose neither. *See also Sharpe Holdings*, 801 F.3d at 942. Likewise, reconsideration of these issues has also led the Departments to conclude that the Mandate imposes a substantial burden on the religious beliefs of an individual employee who opposes coverage of some (or all) contraceptives in his or her plan on the basis of his or her religious beliefs, and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because the Mandate requires that employer or issuer to provide a plan that covers all FDA-approved contraceptives. The Departments disagree with commenters that contend the accommodation did not impose a substantial burden on religiously objecting entities, and agree with other commenters and some courts and judges that concluded the accommodation can be seen as imposing a substantial burden on religious exercise in many instances.

b. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have concluded, after reassessing the relevant interests and, in light of the public comments received, that it does not. This is based on several independent reasons.

First, as discussed above, the structure of section 2713(a)(4) and the ACA evince a desire by Congress to

[16] *See* Federal Law Protections for Religious Liberty, 82 FR 49668, 49669 (Oct. 26, 2017).

grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans pursuant to section 2713(a)(4). This informs the Departments' assessment of whether the interest in mandating the coverage constitutes a compelling interest, as doing so imposes a substantial burden on religious exercise. As the Department of Justice has explained, "[t]he strict scrutiny standard applicable to RFRA is exceptionally demanding," and "[o]nly those interests of the highest order can outweigh legitimate claims to the free exercise of religion, and such interests must be evaluated not in broad generalities but as applied to the particular adherent." [17]

Second, since the day the contraceptive Mandate came into effect in 2011, the Mandate has not applied in many circumstances. To begin, the ACA does not apply the Mandate, or any part of the preventive services coverage requirements, to grandfathered plans. To continue, the Departments under the last Administration provided exemptions to the Mandate and expanded those exemptions through multiple rulemaking processes. Those rulemaking processes included an accommodation that effectively left employees of many non-exempt religious nonprofit entities without contraceptive coverage, in particular with respect to self-insured church plans exempt from ERISA. Under the previous accommodation, once a self-insured church plan filed a self-certification or notice, the accommodation relieved it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would generally have transferred the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments recognized that they lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to health insurance issuers, but does not apply to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs of those plans to provide such coverage, led to significant disparity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

Third party administrators for some, but not all, religious nonprofit organizations were subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they administer a self-insured church plan. Notably, many of those nonprofit organizations were not houses of worship or integrated auxiliaries. Under section 3(33)(C) of ERISA, organizations whose employees participate in self-insured church plans need not be churches so long as they are controlled by or "share[ ] common religious bonds and convictions with" a church or convention or association of churches. The effect is that many similar religious organizations were being treated differently with respect to their employees receiving contraceptive coverage based solely on whether organization employees participate in a church plan.

This arrangement encompassed potentially hundreds of religious non-profit organizations that were not covered by the exemption for houses of worship and integrated auxiliaries. For example, the Departments were sued by two large self-insured church plans—Guidestone and Christian Brothers.[18] Guidestone is a plan organized by the Southern Baptist convention that covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not. Christian Brothers is a plan that covers Catholic churches and integrated auxiliaries and has said in litigation that it covers about 500 additional entities that are not exempt as churches. In several other lawsuits challenging the Mandate, the previous Administration took the position that some plans established and maintained by houses of worship but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government "has no authority to require the plaintiffs' TPAs to provide contraceptive coverage at this time." *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

Third, the Departments now believe the administrative record on which the Mandate rested was—and remains—insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. The Mandate is not narrowly tailored to advance the government's interests and appears both overinclusive and underinclusive. It includes some entities where a contraceptive coverage requirement seems unlikely to be effective, such as religious organizations of certain faiths, which, according to commenters, primarily hire persons who agree with their religious views or make their dedication to their religious views known to potential employees who are expected to respect those views. The Mandate also does not apply to a significant number of entities encompassing many employees and for-profit businesses, such as grandfathered plans. And it does not appear to target the population defined, at the time the Guidelines were developed, as being the most at-risk of unintended pregnancy, that is, "women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority." [19] Rather than focusing on this group, the Mandate is a broad-sweeping requirement across employer-provided coverage and the individual and group health insurance markets.

The Department received conflicting comments on this issue. Some commenters agreed that the government does not have a compelling interest in applying the Mandate to objecting religious employers. They noted that the expanded exemptions will impact only a small fraction of women otherwise affected by the Mandate and argued that refusing to provide those exemptions would fail to satisfy the compelling interest test. Other commenters, however, argued that the government has a broader interest in the Mandate because all women should be considered at-risk of unintended pregnancy. But the Institute of Medicine (IOM), in discussing whether contraceptive coverage is needed, provided a very specific definition of the population of women most at-risk of unintended pregnancy.[20] The Departments believe it is appropriate to consider the government's interest in

[17] *Id.* at 49670.

[18] The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

[19] Institute of Medicine, "Clinical Preventive Services for Women: Closing the Gaps" at 102 (2011).

[20] Id.

the contraceptive coverage requirement using the definition that formed the basis of that requirement and the justifications the Departments have offered for it since 2011. The Mandate, by its own terms, applies not just to women most at-risk of unintended pregnancy as identified by the IOM, but applies to any non-grandfathered "group health plan and a health insurance issuer offering group or individual health insurance coverage." PHS Act section 2713(a). Similarly, the exemptions and accommodation in previous rules, and the expanded exemptions in these rules, do not apply only to coverage for women most at-risk of unintended pregnancy, but to plans where a qualifying objection exists based on sincerely held religious beliefs without regard to the types of women covered in those plans. Seen in this light, the Departments believe there is a serious question whether the administrative record supports the conclusion that the Mandate, as applied to religious objectors encompassed by the expanded exemptions, is narrowly tailored to achieve the interests previously identified by the government. Whether and to what extent it is certain that an interest in health is advanced by refraining from providing expanded religious exemptions is discussed in more detail below in section II.F., Health Effects of Contraception and Pregnancy.

Fourth, the availability of contraceptive coverage from other possible sources—including some objecting entities that are willing to provide some (but not all) contraceptives, or from other governmental programs for low-income women—detracts from the government's interest to refuse to expand exemptions to the Mandate. The Guttmacher Institute recently published a study that concluded, "[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy," and "there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use." [21] In discussing why they did not see such an effect from the Mandate, the authors suggested that "[p]rior to the implementation of the ACA, many women were able to access contraceptive methods at low or no cost through publicly funded family planning centers and Medicaid; existence of these safety net programs may have dampened any impact that the ACA could have had on contraceptive use. In addition, cost is not the only barrier to accessing a full range of method options," and "[t]he fact that income is not associated with use of most other methods [besides male sterilization and withdrawal] obtained through health care settings may reflect broader access to affordable and/or free contraception made possible through programs such as Title X."

Fifth, the Departments previously created the accommodation, in part, as a way to provide for payments of contraceptives and sterilization in a way that is "seamless" with the coverage that eligible employers provide to their plan participants and their beneficiaries. (80 FR 41318). As noted above, some commenters contended that seamlessness between contraceptive coverage and employer sponsored insurance is important and is a compelling governmental interest, while other commenters disagreed. Neither Congress, nor the Departments in other contexts, have concluded that seamlessness, as such, is a compelling interest in the federal government's delivery of contraceptive coverage. For example, the preventive services Mandate itself does not require contraceptive coverage and does not apply to grandfathered plans, thereby failing to guarantee seamless contraceptive coverage. The exemption for houses of worship and integrated auxiliaries, and the application of the accommodation to certain self-insured church plans, also represents a failure to achieve seamless contraceptive coverage. HHS's Title X program provides contraceptive coverage in a way that is not necessarily seamless with beneficiaries' employer sponsored insurance plans. After reviewing the public comments and reconsidering this issue, the Departments no longer believe that if a woman working for an objecting religious employer receives contraceptive access in ways that are not seamless to her employer sponsored insurance, a compelling government interest has nevertheless been undermined. Therefore the Departments conclude that guaranteeing seamlessness between contraceptive access and employer sponsored insurance does not constitute a compelling interest that overrides employers' religious objections to the contraceptive Mandate.

Some commenters contended that obtaining contraceptive coverage from other sources could be more difficult or more expensive for women than obtaining it from their group health plan or health insurance plan. The Departments do not believe that such differences rise to the level of a compelling interest or make it inappropriate for us to issue the expanded exemptions set forth in these final rules. Instead, after considering this issue, the Departments conclude that the religious liberty interests that would be infringed if we do not offer the expanded exemptions are not overridden by the impact on those who will no longer obtain contraceptives through their employer sponsored coverage as a result. This is discussed in more detail in following section, II.D., Burdens on Third Parties.

D. Burdens on Third Parties

The Departments received a number of comments on the question of burdens that these rules might impose on third parties. Some commenters asserted that the expanded exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might not otherwise receive contraceptive coverage with no cost-sharing. These included commenters agreeing with the Departments' explanations in the Religious IFC, stating that unintended pregnancies were decreasing before the Mandate was implemented, and asserting that any benefit that third parties might receive in getting contraceptive coverage does not justify forcing religious persons to provide such products in violation of their beliefs. Other commenters disagreed, asserting that the expanded exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more unintended pregnancies,[22] births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as those found in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as

[21] M.L. Kavanaugh et al., Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014, 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

[22] Some commenters attempted to quantify the costs of unintended pregnancy, but failed to persuasively estimate the population of women that this exemption may affect.

prioritizing religious liberty of exempted entities over the religious liberty, conscience, or choices of women who would not receive contraceptive coverage where an exemption is used.

The Departments note that the exemptions in the Religious IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these final rules do not create a governmental burden: rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. HHS exercised discretion granted to HRSA by the Congress to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties who the government chose not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: that the government has an obligation to force private parties to benefit those third parties and that the third parties have a right to those benefits. But Congress did not create a right to receive contraceptive coverage from other private citizens through PHS Act section 2713, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to benefit other private parties, does not prevent the government from relieving some or all of the burden of its Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Religious IFC and these rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third-party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris* v. *McRae*, 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the Government refrain from requiring private citizens, in violation of their religious beliefs, to cover contraception for other citizens. *Cf. Rust* v. *Sullivan*, 500 U.S. 173, 192–93 (1991) ("A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity."). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting religious objections to such governmental mandates, especially where, as here, the mandate is not an explicit statutory requirement.[23] The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these final rules.

As the Department of Justice has observed, the fact that exemptions may relieve a religious adherent from conferring a benefit on a third party "does not categorically render an exemption unavailable," and RFRA still applies.[24] The Departments conclusion on this matter is consistent with the Supreme Court's observation that RFRA may require exemptions even from laws requiring claimants "to confer benefits on third parties." *See Hobby Lobby*, 134 S. Ct. at 2781 n.37. Here, no law contains such a requirement, but the Mandate is derived from an administrative exercise of discretion that Congress charged HRSA and the Departments with exercising. Burdens that may affect third parties as a result of revisiting the exercise of agency discretion may be relevant to the RFRA analysis, but they cannot be dispositive. "Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants)." *Id.*

When government relieves burdens on religious exercise, it does not violate the Establishment Clause: rather, "it follows the best of our traditions." *Zorach* v. *Clauson*, 343 U.S. 306, 314 (1952). The Supreme Court's cases "leave no doubt that in commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice." *Board of Educ. of Kiryas Joel Village Sch. Dist.* v. *Grumet*, 512 U.S. 687, 705 (1994). Rather, the Supreme Court "has long recognized that the government may (and sometimes must) accommodate religious practices and that it may do so without violating the Establishment Clause." *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos*, 483 U.S. 327, 334 (1987) (quoting *Hobbie* v. *Unemployment Appeals Comm'n of Fla.*, 480 U.S. 136, 144–45 (1987)). "[T]here is room for play in the joints between the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause." *Cutter* v. *Wilkinson*, 544 U.S. 709, 713 (2005) (internal quotation omitted). Thus, the Supreme Court has upheld a broad range of accommodations against Establishment Clause challenges, including the exemption of religious organizations from Title VII's prohibition against discrimination in employment on the basis of religion, *see Amos*, 483 U.S. at 335–39; a state property tax exemption for religious organizations, *see Walz* v. *Tax Comm'n of City of New York*, 397 U.S. 664, 672–80 (1970); and a state program releasing public school children during the school day to receive religious instruction at religious centers, *see Zorach*, 343 U.S. at 315.

Before 2012 (when HRSA's Guidelines went into effect), there was no federal women's preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA's Guidelines, and it did not require any preventive services required under PHS

[23] *See, for example, Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011) ("[A] woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.").

[24] See Federal Law Protections for Religious Liberty, 82 FR at 49670.

Act section 2713 to be covered by grandfathered plans. Many States do not impose contraceptive coverage mandates, or they offer religious exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or State courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters said that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others said that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to states or local governments. We are not aware of instances where the various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage (other than through the Religious and Moral IFCs), have been determined to cause a cognizable injury to state or local governments. Some states that were opposed to the IFCs submitted comments objecting to the potential impacts on their programs resulting from the expanded exemptions, but they did not adequately demonstrate that such impacts would occur, and they did not explain whether, or to what extent, they were impacted by the other kinds of instances mentioned above in which no federal mandate of contraceptive coverage has applied to certain plans. The Departments find no legal prohibition on finalizing these rules based on the speculative suggestion of an impact on state or local governments, and we disagree with the suggestion that once we have exercised our discretion to deny exemptions—no matter how recently or incompletely—we cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, these expanded exemptions apply only to a small fraction of entities to which the Mandate would otherwise apply—those with qualifying religious objections. Public comments did not provide reliable data on how many entities would use these expanded religious exemptions, in which states women in such plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would have to cover. As mentioned above, at least one study, published by the Guttmacher Institute, concluded the Mandate has caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the expanded exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates.

In the discussion below concerning estimated economic impacts of these rules, the Departments explain there is not reliable data available to accurately estimate the number of women who may lose contraceptive coverage under these rules, and the Departments set forth various reasons why it is difficult to know how many entities will use these exemptions or how many women will be impacted by those decisions. Solely for the purposes of determining whether the rules have a significant economic impact under Executive Order 12,866, and in order to estimate the broadest possible impact so as to determine the applicability of the procedures set forth in that Executive Order, the Departments propose that the rules will affect no more than 126,400 women of childbearing age who use contraceptives covered by the Guidelines, and conclude the economic impact falls well below $100 million. As explained below, that estimate assumes that a certain percentage of employers which did not cover contraceptives before the ACA will use these exemptions based on sincerely held religious beliefs. The Departments do not actually know that such entities will do so, however, or that they operate based on sincerely held religious beliefs against contraceptive coverage. The Departments also explain that other exemptions unaffected by these rules may encompass many or most women potentially affected by the expanded exemptions. In other words, the houses of worship and integrated auxiliaries exemption, the accommodation's failure to require contraceptive coverage in certain self-insured church plans, the non-applicability of PHS Act section 2713 to grandfathered plans, and the permanent injunctive relief many religious litigants have received against section 2713(a)(4), may encompass a large percentage of women potentially affected by religious objections, and therefore many women in those plans may not be impacted by these rules at all. In addition, even if 126,400 women might be affected by these rules, that number constitutes less than 0.1% of all women in the United States.[25] This suggests that if these rules have any impact on state or local governments, it will be statistically de minimus. The Departments conclude that there is insufficient evidence of a potential negative impact of these rules on state and local governments to override the appropriateness of deciding to finalize these rules.

Some commenters contended that the expanded exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions

[25] U.S. Census Bureau, "Quick Facts: Population Estimates, July 1, 2017" (estimating 325,719,178 persons in the U.S., 50.8% of which are female), available at *https://www.census.gov/quickfacts/fact/table/US/PST045217*.

would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these final rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The expanded exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead they allow entities that have sincerely held religious objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

These commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.*, 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII "does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women"). Second, these rules create no disparate impact. The women's preventive services mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inures to the specific benefit of women—men are denied any benefit from that section. Both before and after these final rules, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or male contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions are expanded to encompass religious objections. The previous regulations, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that few women of childbearing age in the country will be affected by these expanded exemptions.[26] In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby*'s holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters observed that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some objected to the suggestion in the Religious IFC that many forms of contraceptives are available for around $50 per month and other forms, though they bear a higher one-time cost, cost a similar amount over the duration of use. But some of those commenters cited sources maintaining that birth control pills can cost up to $600 per year (that is, $50 per month), and said that IUDs, which can last three to six years or more,[27] can cost $1,100 (that is, less than $50 per month over the duration of use). Some commenters said that, for lower income women, contraceptives can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately insured individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, pointing out that some government programs that provide family planning have income and eligibility thresholds, so that women earning certain amounts above those levels would need to pay full cost for contraceptives if they were no longer covered in their health plans.

The Departments do not believe that these general considerations make it inappropriate to issue the expanded exemptions set forth in these rules. In addition, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed regulation to amend the regulations governing its Title X family planning program. The proposed regulation would amend the definition of "low income family"—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions (see 83 FR 25502). If that regulation is finalized as proposed, it could further reduce any potential effect of these final rules on women's access to contraceptives. That proposal also demonstrates that the government has other means available to it for increasing women's access to contraception. Some of those means are less restrictive of religious exercise than imposition of the contraceptive Mandate on employers with sincerely held religious objections to providing such coverage.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS "shall not promulgate any regulation" that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impedes timely access to health care services," "interferes with communications regarding a full range of treatment options between the patient and the provider." "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," "violates the principles of informed consent and the ethical standards of health care professionals," or "limits the

[26] Below, the Departments estimate that no more than 126,400 women of childbearing age will be affected by the expanded exemptions. As noted above, this is less than 0.1% of the over 165 million women in the United States. The Departments previously estimated that, at most 120,000 women of childbearing age would be affected by the expanded exemptions. *See* Religious IFC, 82 FR 47,823–84.

[27] *See, for example*, Planned Parenthood, "IUD." *https://www.plannedparenthood.org/learn/birth-control/iud.*

availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. 18114. Such commenters urged, for example, that the Religious IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections. The Departments, which administer both ACA section 1554 and PHS Act section 2713, did not conclude that the exemptions or accommodations in those regulations violated section 1554. Moreover, the decision not to impose a governmental mandate is not the "creation" of a "barrier," especially when that mandate requires private citizens to provide services to other private citizens. Nor, in any event, are the exemptions from the Mandate unreasonable. Section 1554 of the ACA does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 prohibit the Departments from providing exemptions for burdens on religious exercise, or, as is the case here, from refraining to impose the Mandate in cases where religious exercise would be burdened by it. In light of RFRA and the First Amendment, providing religious exemptions is a reasonable administrative response in the context of this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts. Religious exemptions from federal mandates in sensitive health contexts have existed in federal laws for decades, and President Obama referenced them when he issued Executive Order 13535 (March 24, 2010), declaring that, under the ACA, "longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact," and that "[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS." While the text of Executive Order 13535 does not require the expanded exemptions issued in these rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect religious beliefs.

In short, the Departments do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

Members of the public have widely divergent views on whether expanding the exemptions is good public policy. Some commenters said the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind expanding the exemptions and arguing that the exemptions would not interfere with the physician-patient relationship. For all the reasons explained at length in this preamble, the Departments have determined that these rules are good policy. Because of the importance of the religious liberty values being accommodated, the limited impact of these rules, and uncertainty about the impact of the Mandate overall according to some studies, the Departments do not believe these rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

E. Interim Final Rulemaking

The Departments received several comments about their decision to issue the Religious IFC as interim final rules with requests for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Religious IFC in that way, agreeing that the Departments had explicit statutory authority to do so, good cause under the Administrative Procedure Act (APA), or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe legal authority existed to issue the Religious IFC as interim final rules. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Religious IFC, the Departments issued three interim final rules implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Religious IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Religious IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules are being issued after receiving and thoroughly considering public comments as requested in the Religious IFC. These final rules therefore comply with the APA's notice and comment requirements.

F. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause or are associated with an increased risk of depression,[28] venous thromboembolic

[28] Commenters cited Charlotte Wessel Skovlund et al., "Association of Hormonal Contraception with Depression," 73 *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) ("Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression,

disease,[29] fatal pulmonary embolism,[30] thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),[31] hypertension,[32] HIV–1 acquisition and transmission,[33] and breast, cervical, and liver cancers.[34] Some commenters also observed that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that contraceptive access does not reduce unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 IOM Report's discussions of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality.[35] Commenters also said studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer,[36] and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.[37] Some commenters said that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters said that, in the Religious IFC, the Departments made incorrect statements concerning scientific studies. For example, some commenters argued there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Religious IFC for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality Report No.: 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR at 47804, the 2013 Agency for Healthcare Research and Quality study, and others, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to take into account both of those studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,[38] the purpose for the Departments' reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or, more specifically, the part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some

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suggesting depression as a potential adverse effect of hormonal contraceptive use.").

[29] Commenters cited the Practice Committee of the American Society for Reproductive Medicine, "Hormonal Contraception: Recent Advances and Controversies," 82 *Fertility and Sterility* S20, S26 (2004); V.A. Van Hylckama et al., "The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study," 339 *Brit. Med. J.* 339b2921 (2009); Y. Vinogradova et al., "Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases," 350 *Brit. Med. J.* 350h2135 (2015) ("Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year."); Ø. Lidegaard et al., "Hormonal contraception and risk of venous thromboembolism: national follow-up study," 339 *Brit. Med. J.* b2890 (2009); M. de Bastos et al., "Combined oral contraceptives: venous thrombosis," Cochrane Database Syst. Rev. (no. 3, 2014), CD010813. doi: 10.1002/14651858.CD010813.pub2, available at *https://www.ncbi.nlm.nih.gov/pubmed?term=24590565;* L.J Havrilesky et al., "Oral Contraceptive User for the Primary Prevention of Ovarian Cancer," Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* and Robert A. Hatcher et al., *Contraceptive Technology* 405–07 (Ardent Media 18th rev. ed. 2004).

[30] Commenters cited N.R. Poulter, "Risk of Fatal Pulmonary Embolism with Oral Contraceptives," 355 *Lancet* 2088 (2000).

[31] Commenters cited Ø. Lidegaard et al., "Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception," 366 *N. Eng. J. Med.* 2257, 2257 (2012) (risks "increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 μg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 μg"); Practice Committee of the American Society for Reproductive Medicine, "Hormonal Contraception"; M. Vessey et al., "Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking," 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, "Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study," 349 *Lancet* 1202, 1202–09(1997); K.M. Curtis et al., Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review, 73 Contraception 73179, 179–88 (2006); L.A. Gillum et al., "Ischemic stroke risk with oral contraceptives: A meta analysis," 284 *JAMA* 72, 72–78 (2000), available at *https://www.ncbi.nlm.nih.gov/pubmed/10872016;* and Robert A. Hatcher et al., *Contraceptive Technology* 404–05, 445 (Ardent Media 18th rev. ed. 2004).

[32] Commenters cited Robert A. Hatcher et al., *Contraceptive Technology* 407, 445 (Ardent Media 18th rev. ed. 2004).

[33] Commenters cited Renee Heffron et al., "Use of Hormonal Contraceptives and Risk of HIV–1 Transmission: A Prospective Cohort Study," 12 *Lancet Infectious Diseases 19, 24* (2012) ("Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV–1 acquisition by women and HIV–1 transmission from women to men."); and "Hormonal Contraception Doubles HIV Risk, Study Suggests," *Science Daily* (Oct. 4, 2011), *https://www.sciencedaily.com/releases/2011/10/111003195253.htm.*

[34] Commenters cited "Oral Contraceptives and Cancer Risk" (Mar. 21, 2012, National Cancer Institute (reviewed Feb. 22, 2018), *https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet;* L.J Havrilesky et al., "Oral Contraceptive User for the Primary Prevention of Ovarian Cancer," Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* S.N. Bhupathiraju et al., "Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study," 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, "The Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment", World Health Organization (Sept. 2005), *http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf;* and the American Cancer Society, "Known and Probably Human Carcinogens," American Cancer Society (rev. Nov. 3, 2016), *https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html.*

[35] Citing, *e.g.*, Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. JAMA 2006;295:1809–23, and John Hopkins Bloomberg Public Health School of Health, Contraception Use Averts 272,000 Maternal Deaths Worldwide, *https://www.jhsph.edu/news/news-releases/2012/ahmed-contraception.html.*

[36] Citing, *e.g.*, Schindler, A.E. (2013). Non-contraceptive benefits of oral hormonal contraceptives. International Journal of Endocrinology and Metabolism, 11 (1), 41–47.

[37] Citing, *e.g.*, id., and American College of Obstetricians and Gynecologists, Committee on Health Care for Underserved Women. (2015, January). Committee Opinion Number 615: Access to Contraception. As discussed below, to the extent that contraceptives are prescribed to treat existing health conditions, and not for preventive purposes, the Mandate would not be applicable.

[38] 82 FR at 47803–04.

commenters agreed with the quotation, in the Religious IFC, of FDA materials [39] that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Religious IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Religious IFC that some persons believe those possible effects are "abortifacient."

The objection on this issue appears to be partially one of semantics. People disagree about whether to define "conception" or "pregnancy" to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items "abortifacient"—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother's body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby,* 134 U.S. at 2765 ("The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.").

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere religious objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of a sincerely held religious belief under RFRA.[40] Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA's statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer expanded religious exemptions with respect to this Mandate.

The Departments also received comments about their discussion of the uncertain effects of the expanded exemptions on teen sexual activity. In this respect, the Departments stated, "With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that '[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.'" [41] Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that denying expanded exemptions to the Mandate is not a narrowly tailored way to advance the Government's interests in reducing teen pregnancy, and suggesting there are means of doing so that are less restrictive of religious exercise.[42] Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.[43]

Many commenters opposing the Religious IFC misunderstood the Departments' discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, we note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general support the Departments' conclusion that it is difficult to establish causation between granting religious exemptions to the contraceptive Mandate and either an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including but not limited to reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline), and concluded "that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny." [44] One

[39] FDA's guide "Birth Control: Medicines To Help You," specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and "may also work . . . by preventing attachment (implantation) to the womb (uterus)" of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

[40] "Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You." *Hobby Lobby,* 134 S. Ct. at 2762–63. "The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point." *Id.* at 2765–66.

[41] Citing J.S. Santelli & A.J. Melnikas, "Teen fertility in transition: recent and historic trends in the United States," 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at *http://public.econ.duke.edu/~psarcidi/addicted13.pdf. See also* K. Buckles & D. Hungerman, "The Incidental Fertility Effects of School Condom Distribution Programs," *Nat'l Bureau of Econ. Research* Working Paper No. 22322 (June 2016), available at *http://www.nber.org/papers/w22322* ("access to condoms in schools increases teen fertility by about 10 percent" and increased sexually transmitted infections).

[42] *See* Helen Alvaré, "No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom," 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[43] *See, for example,* Lindberg L., Santelli J., "Understanding the Decline in Adolescent Fertility in the United States, 2007–2012," 59 *J. Adolescent Health* 577–83 (Nov. 2016), *https://doi.org/10.1016/j.jadohealth.2016.06.024; see also* Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, *www.regulations.gov* (discussing teen pregnancy data from Colorado).

[44] Kearney MS and Levine PB, "Investigating recent trends in the U.S. birth rate," 41 *J. Health*

study found that during the teen pregnancy decline between 2007–2012, teen sexual activity was also decreasing.[45] One study concluded that falling unemployment rates in the 1990s accounted for 85% of the decrease in rates of first births among 18–19 year-old African Americans.[46] Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.[47] One study concluded that an "increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy." [48] Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.[49] Some commenters also cited studies, which are not limited to the issue of teen pregnancy, that have found many women who have abortions report that they were using contraceptives when they became pregnant.[50]

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of the public comments has reinforced the Departments' conclusion that significantly more uncertainty and ambiguity exists on these issues than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals. The uncertainty surrounding these weighty and important issues makes it appropriate to maintain the expanded exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing religious exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments for implementing the ACA.

G. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promotes the health and equality of women, especially low income women and promotes female participation and equality in the workforce. Other commenters contended that there was insufficient evidence that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed the study quoted above, published and revised by the Guttmacher Institute in October 2017, concluding that through 2014 there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy, that there was no significant shift from less effective to more effective methods, and that it was "unclear" whether this Mandate impacted contraceptive use because there was no significant increase in the use of contraceptive methods the Mandate covered.[51] These commenters also noted that, in the 29 States where contraceptive coverage mandates have been imposed statewide,[52] those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[53] Other commenters, however, disputed the significance of these state statistics, noting that of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the expanded exemptions in these rules might have on the Mandate more broadly. The state mandates apply to a very large number of plans and plan participants, notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups are, and have been, exempt from the federal Mandate prior to the Religious IFC. The exemptions as set forth in the Religious IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might

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Econ. 15–29 (2015), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041.*

[45] *See, for example,* K. Ethier et al., "Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015," 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at *http://dx.doi.org/10.15585/mmwr.mm665152a1* ("Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall. . . .").

[46] Colen CG, Geronimus AT, and Phipps MG, "Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States," 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at *https://www.sciencedirect.com/science/article/pii/S027795360600205X.*

[47] Atkins DN and Wilkins VM, "Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates," 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at *https://academic.oup.com/jpart/article-abstract/23/4/771/963674.*

[48] E. Collins & B. Herchbein, "The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act," *U. Mich. Pop. Studies Ctr.* Report 11–737 (May 2011), available at *https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf* ("[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women").

[49] *See* D. Paton & L. Wright, "The effect of spending cuts on teen pregnancy," 54 *J. Health Econ.* 135, 135–46 (2017), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551* ("Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates").

[50] Commenters cited, for example, Guttmacher Institute, "Fact Sheet: Induced Abortion in the United States" (Jan. 2018) ("Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant"), available at *https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.*

[51] Kavanaugh, 97 *Contraception* at 14–21.

[52] *See* Guttmacher Institute, "Insurance Coverage of Contraceptives" (June 11, 2018); Kaiser Family Foundation, "State Requirements for Insurance Coverage of Contraceptives," Henry J Kaiser Family Foundation (Jan. 1, 2018), *https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[53] *See* Michael J. New, "Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes," 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

result from a broad contraceptive coverage mandate.

Some commenters expressed concern that providing exemptions to the Mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, PHS Act section 2713(a)(2) requires coverage of "immunizations," and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting religious beliefs from certain health care mandates concerning issues such as sterilization, abortion and birth control.

Some commenters took issue with the conclusion set forth in the Religious IFC, which is similar to that asserted in the 2017 Guttmacher study, that "[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA." They observed that more women have coverage of contraceptives and contraception counseling under the Mandate and that more contraceptives are provided without co-pays than before. Still other commenters argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters lamented that exemptions would include exemption from the requirement to cover contraception counseling. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA [54] and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also argued that studies show that decreases in unintended pregnancies are due to broader access of contraceptives. Finally, some commenters argued that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on our review, it is not clear that merely expanding exemptions as done in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from birth control access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, we conclude that the Religious IFC and these final rules—which merely withdraw the Mandate's requirement from what appears to be a small group of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. We also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, are an appropriate exercise of the Departments' discretion.

Moreover, we conclude that the best way to balance the various policy interests at stake in the Religious IFC and these final rules is to provide the expanded exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules will provide tangible protections for religious liberty, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a substantial burden on their religious exercise. The Departments view the provision of those protections to preserve religious exercise in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for religious exercise set forth in the Religious IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

[54] Citing, for example, Adelle Simmons et al., "The Affordable Care Act: Promoting Better Health for Women," Table 1, Assistant Secretary for Planning and Evaluation (June 14, 2016). *https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf.*

III. Description of the Text of the Regulations and Response to Additional Public Comments

Here, the Departments describe the regulatory text set forth prior to the Religious IFC, the regulations from that IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments' response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. As noted above, various members of the public provided comments that were supportive, or critical, of the Religious IFC overall, or of significant policies pertaining to those regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

A. Restatement of Statutory Requirements of PHS Act Section 2713(a) and (a)(4) (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv). 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified these restatements to more closely align them with the text of PHS Act section 2713(a) and (a)(4).

Previous versions of these rules had varied from the statutory language. PHS Act section 2713(a) and (a)(4) require group health plans and health insurance issuers offering coverage to provide coverage without cost sharing for "such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines" supported by HRSA. In comparison, the previous version of regulatory restatements of this language (as drawn from 45 CFR 147.130(a)(1)

and (a)(1)(iv)) stated the coverage must include "evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by" HRSA. The Religious IFC amended this language to state, parallel to the language in section 2713(a)(4), that the coverage must include "such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by" HRSA.

These rules adopt as final, without change, the provisions in the Religious IFC amending 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). In this way, the regulatory text better conforms to the statutory language. In paragraph (a)(1) of the final regulations, instead of saying "must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements . . . with respect to those items and services:", the regulation now tracks the statutory language by saying "must provide coverage for and must not impose any cost-sharing requirements . . . for—". By eliminating the language "coverage for all of the following items and services," and "with respect to those items and services," the Departments do not intend that coverage for specified items and services will not be required, but we simply intend to simplify the text of the regulation to track the statute and avoid duplicative language.

By specifying that paragraph (a)(1)(iv) concerning the women's preventive services Guidelines encompasses "such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132," the regulatory text also better tracks the statutory language that the Guidelines are for "such additional" preventive services as HRSA may "provide[ ] for" and "support[ ]." This text also eliminates language, not found in the statute, that the Guidelines are "evidence-informed" and "binding." Congress did not include the word "binding" in PHS Act section 2713, and did include the words "evidence-based" or "evidence-informed" in section 2713(a)(1) and (a)(3), but omitted such terms from section 2713(a)(4). In this way, the regulatory text better comports with the scope of the statutory text. This text of paragraph (a)(1)(iv) also acknowledges that the Departments have decided Guidelines issued under section 2713(a)(4) will not be provided for or supported to the extent they exceed the exemptions and accommodation set forth in 45 CFR 147.131 and 147.132. Previous versions of the regulation placed that limit in 45 CFR 147.130(a)(1), but did not reiterate it in § 147.130(a)(1)(iv). To clearly set forth the applicability of the exemptions and accommodation, the Departments adopt as final the Religious IFC language, which included the language "subject to §§ 147.131 and 147.132" in both § 147.130(a)(1) and § 147.130(a)(1)(iv). Because these final rules adopt as final the Religious IFC language which includes the exemptions and accommodation in both §§ 147.131 and 147.132, and not just in § 147.131 as under the previous rules, the Departments correspondingly included references to both sections in this part.

Some commenters supported restoring the statutory language from PHS Act section 2713(a) and (a)(4) in the regulatory restatements of that language. Other commenters opposed doing so, asserting that Guidelines issued pursuant to section 2713(a)(4) must be "evidence-informed" and "binding." The Departments disagree with the position that, even though Congress omitted those terms from section 2713(a)(4), their regulatory restatement of the statutory requirement should include those terms. Instead, the Departments conclude that it is more appropriate for the regulatory restatements of section 2713(a)(4) to track the statutory language in this regard, namely, "as provided for in comprehensive guidelines supported by [HRSA] for purposes of" that paragraph.

B. Prefatory Language of Religious Exemptions (45 CFR 147.132(a)(1))

These final rules adopt as final, with changes based on comments as set forth below, the regulatory provision in the Religious IFC that moved the religious exemption from 45 CFR 147.131(a) to 45 CFR 147.132.

In the previous regulations, the exemption stated, at § 147.131(a), that HRSA's Guidelines "may establish an exemption" for the health plan or coverage of a "religious employer," defined as "an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code." The Religious IFC moved the exemption to a new § 147.132, in which paragraph (a) discussed objecting entities, paragraph (b) discussed objecting individuals, paragraph (c) set forth a definition, and paragraph (d) discussed severability. The prefatory language to § 147.132(a)(1) stated that HRSA's Guidelines "must not provide for or support the requirement of coverage or payments for contraceptive services" for the health plan or coverage of an "objecting organization," and thus that HRSA "will exempt" such an organization from the contraceptive coverage requirments of the Guidelines. The remainder of paragraph (a)(1), which is discussed in greater detail below, describes what entities are included as objecting organizations.

This language not only specifies that certain entities are "exempt," but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women's preventive services coverage only "as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are "exempt" by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as "exempt," and in referring to the "exemption" encompassing those entities or plans, the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior regulations have worked by means of similar language. When sections § 147.132(a)(1) and (a)(1)(i) specify that "[a] group health plan," "health insurance coverage provided in connection with a group health plan," and "health insurance coverage offered or arranged by an objecting organization" are exempt "to the extent" of the objections "as specified in paragraph (a)(2)," that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv)), the plan

sponsor, issuer, and plan covered in the exemption of § 147.132(a)(1) and (a)(1)(i) would face no penalty as a result of omitting certain contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while the objection of a plan sponsor (or entity that arranges coverage under the plan, as applicable) removes penalties from that plan's issuer, it only does so for that plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.132(a)(1)(iii) is included below.

The exemptions in § 147.132(a)(1) apply "to the extent" of the objecting entities' sincerely held religious convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters said it was unclear whether the plans of entities or individuals that religiously object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite religious objection against some but not all contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects, and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules, the Departments finalize the prefatory language of § 147.132(a) with the following change, so that the final rules state that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, "to the extent of the objections specified below."

The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying "to the extent" of the objection(s).

C. Scope of Religious Exemptions and Requirements for Exempt Entities (45 CFR 147.132)

In 45 CFR 147.132(a)(1)(i) through (iii) and (b), the Religious IFC expands the exemption to plans of additional entities and individuals not encompassed by the exemption set forth in the regulations prior to the Religious IFC. Specific entities to which the expanded exemptions apply are discussed below.

The exemptions contained in previous regulations, at § 147.131(a), did not require exempt entities to submit any particular self-certification or notice, either to the government or to their issuer or third party administrator, in order to obtain or qualify for the exemption. Similarly, under the expanded exemptions in § 147.132, the Religious IFC did not require exempt entities to comply with a self-certification process. We finalize that approach in this respect without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[55] Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosure documents must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported the expanded exemption's approach which maintained the policy of the previous exemption in not requiring exempt entities to comply with a self-certification process. They suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to religious objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters, however, favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process. Some commenters asked that the government publish a list of entities that claim the exemption.

The Departments believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption. The Departments believe the approach under the previous exemption is appropriate for the expanded exemption. Adding a self-certification or notice to the exemption process would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices were to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries in plans that reduce or eliminate contraceptive benefits as a result of the exemption will know whether their health plan claims an exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these rules to continue to not require notices or self-certifications for using the exemption.

[55] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 102–3, & 104b–3(d), and 29 CFR 2590.715–2715. *See also* 45 CFR 147.200 (requiring disclosure of the "exceptions, reductions, and limitations of the coverage," including group health plans and group and individual issuers).

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these rules. The expanded exemptions in these rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. The rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (Below, these rules discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that, where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed below, the Departments are including, in these final rules, language from the previous regulations protecting issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in and derived from the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators.

Regarding the Religious IFC's expansion of the exemption to other kinds of entities and individuals in general, commenters disagreed about the likely effects of the exemptions on the health coverage market. Some commenters said that expanding the exemptions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or offer only some contraceptives—to houses of worship and integrated auxiliaries; some commenters and litigants said that issuers were doing so. These cases where plans did not need to comply with the Mandate, and the Departments' previous accommodation process allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.[56]

Concerning the prospect raised by commenters of different risk pools between men and women, PHS Act section 2713(a) itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage would be required. These rules do not require issuers to offer products that satisfy religiously objecting entities or individuals; they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to religious entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

[56] *See also Real Alternatives* v. *Sec'y, Dep't of Health & Human Servs.*, 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) ("Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny." (citation and internal quotation marks omitted)).

D. Plan Sponsors in General (45 CFR 147.132(a)(1)(i) Prefatory Text)

With respect to employers and others that sponsor group health plans, in § 147.132(a)(1)(i), the Religious IFC provided exemptions for non-governmental plan sponsors that object to coverage of all, or a subset of, contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs. The Departments finalize the prefatory text of § 147.132(a)(1)(i) without change.

The expanded exemptions covered any kind of non-governmental employer plan sponsor with the requisite objections, stating the exemption encompassed "[a] group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section." For the sake of clarity, the expanded exemptions also stated that "[s]uch non-governmental plan sponsors include, but are not limited to, the following entities," followed by an illustrative, non-exhaustive list of non-governmental organizations whose objections qualify the plans they sponsor for an exemption. Each type of such entities, and comments specifically concerning them, are discussed below.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.132(a)(1)(i). Some commenters suggested that the expanded religious exemptions should include government entities. Others disagreed. The Departments are not aware of reasons why it would be appropriate or necessary to offer a religious exemption to governmental employer plan sponsors with respect to the contraceptive Mandate. We are unaware of government entities that would attempt to assert a religious exemption to the Mandate, and it is not clear to us that a governmental entity could do so. Accordingly, we conclude that it is appropriate for us to not further expand the religious exemption to include governmental entities in the religious plan-sponsor exemption.

Nevertheless, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and, thus, to provide

health coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union, or a sponsor of a multiemployer plan) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization. Some commenters objected to extending the exemption to such entities, arguing that they could not have the same kind of religious objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite religious objection. The Departments conclude that it is appropriate, where the plan sponsor of a union, multiemployer, or similar plan adopts a religious objection using the same procedures that such a plan sponsor might use to make other decisions, that the expanded exemptions should respect that decision by providing an exemption from the Mandate.

E. Houses of Worship and Integrated Auxiliaries (45 CFR 147.132(a)(1)(i)(A))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only "an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended." Section 6033(a)(3)(A)(i) or (iii) of the Code encompasses "churches, their integrated auxiliaries, and conventions or associations of churches," and "the exclusively religious activities of any religious order."

The Religious IFC expanded the exemption to include, in § 147.132(a)(1)(i)(A), plans sponsored by "[a] church, an integrated auxiliary of a church, a convention or association of churches, or a religious order." Most commenters did not oppose the exemptions continuing to include these entities, although some contended that the Departments have no authority to exempt any entity or plan from the Mandate, an objection to which the Departments respond above. Notably, this exemption exempts "a religious order," and not merely "the exclusively religious activities of any religious order." In addition, section 6033(a)(3)(A)(i) specifies that it covers churches, not merely "the exclusively religious activities" of a church. Some religious people might express their beliefs through a church, others might do so through a religious order, and still others might do so through religious bodies that take a different form, structure, or nomenclature based on a different cultural or historical tradition. *Cf. Hosanna-Tabor Evangelical Lutheran Church and School* v. *E.E.O.C.*, 565 U.S. 171, 198 (2012) (Alito and Kagan, JJ., concurring) ("The term 'minister' is commonly used by many Protestant denominations to refer to members of their clergy, but the term is rarely if ever used in this way by Catholics, Jews, Muslims, Hindus, or Buddhists."). For the purposes of respecting the exercise of religious beliefs, which the expanded exemptions in these rules concern, the Departments find it appropriate that this part of the exemption encompasses religious orders and churches similarly, without limiting the scope of the protection to the exclusively religious activities of either kind of entity. Based on all these considerations, the Departments finalize § 147.132(a)(1)(i)(A) without change.

Moreover, the Departments also finalize the regulatory text to exempt plans "established or maintained by" a house of worship or integrated auxiliary on a plan, not employer, basis. Under previous regulations, the Departments stated that "the availability of the exemption or accommodation [was to] be determined on *an employer by employer basis,* which the Departments . . . believe[d] best balance[d] the interests of religious employers and eligible organizations and those of employees and their dependents." (78 FR 39886 (emphasis added)). Therefore, under the prior exemption, if an employer participated in a house of worship's plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not covered by the exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a "plan established or maintained by a [house of worship]." Upon further consideration, in the Religious IFC, the Departments changed their view on this issue and expanded the exemption for houses of worship and integrated auxiliaries. Under these rules, the Departments intend that, when this regulation text exempts a plan "established or maintained by" a house of worship or integrated auxiliary, such exemption will no longer "be determined on an employer by employer basis," but will be determined on a plan basis—that is, by whether the plan is a "plan established or maintained by" a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices, but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the requirement of being integrated auxiliaries. Under this interpretation, houses of worship would not be faced with the potential of having to include, in the plans that they have established and maintained, coverage for services to which they have a religious objection for employees of an affiliated employer participating in the plans.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted to participate in its health plan but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior regulation where with respect to self-insured church plans, hundreds of nonprofit religious entities participating in those plans were provided a mechanism by which their plan participants would not receive contraceptive coverage through the plan or third party administrator.[57]

Therefore, the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

F. Nonprofit Organizations (45 CFR 147.132(a)(1)(i)(B))

The exemption under previous regulations did not encompass nonprofit religious organizations beyond one that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code. The Religious IFC expanded the exemption to include plans sponsored by any other

[57] See supra at II.A.3.

"nonprofit organization," § 147.132(a)(1)(i)(B), if it has the requisite religious objection under § 147.132(a)(2) (see § 147.132(a)(1)(i) introductory text). The Religious IFC also specified in § 147.132(a)(1)(i)(A), as under the prior exemption, that the exemption covers "a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order." (Hereinafter "houses of worship and integrated auxiliaries.") These rules finalize, without change, the text of § 147.132(a)(1)(i)(A) and (B).

The Departments received comments in support of, and in opposition to, this expansion. Some commenters supported the expansion of the exemptions beyond houses of worship and integrated auxiliaries to other nonprofit organizations with religious objections (referred to herein as "religious nonprofit" organizations, groups or employers). They said that religious belief and exercise in American law has not been limited to worship, that religious people engage in service and social engagement as part of their religious exercise, and, therefore, that the Departments should respect the religiosity of nonprofit groups even when they are not houses of worship and integrated auxiliaries. Some public commenters and litigants have indicated that various religious nonprofit groups possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Other commenters did not support the expansion of exemptions to nonprofit organizations. Some of them described churches as having a special status that should not be extended to religious nonprofit groups. Some others contended that women at nonprofit religious organizations may support or wish to use contraceptives and that if the exemptions are expanded, it would deprive all or most of the employees of various religious nonprofit organizations of contraceptive coverage.

After evaluating the comments, the Departments continue to believe that an expanded exemption is the appropriate administrative response to the substantial burdens on sincere religious beliefs imposed by the contraceptive Mandate, as well as to the litigation objecting to the same. We agree with the comments that religious exercise in this country has long been understood to encompass actions outside of houses of worship and their integrated auxiliaries. The Departments' previous assertion that the exemptions were intended to respect a certain sphere of church autonomy (80 FR 41325) is not, in itself, grounds to refuse to extend the exemptions to other nonprofit entities with religious objections. Respect for churches does not preclude respect for other religious entities. Among religious nonprofit organizations, the Departments no longer adhere to our previous assertion that "[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection." (78 FR 39874.) It is not clear to the Departments that the percentage of women who work at churches that oppose contraception, but who support contraception, is lower than the percentage of woman who work at nonprofit religious organizations that oppose contraception on religious grounds, but who support contraception. In addition, public comments and litigation reflect that many nonprofit religious organizations publicly describe their religiosity. Government records and those groups' websites also often reflect those groups' religious character. If a person who desires contraceptive coverage works at a nonprofit religious organization, the Departments believe it is sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit religious organization that opposes contraceptive coverage to hire a person who the organization knows disagrees with the organization's view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[58]

In addition, it is not at all clear to the Departments that expanding the exemptions would, as some commenters asserted, remove contraceptive coverage from employees of many large religious nonprofit organizations. Many large religious nonprofit employers, including but not limited to some Catholic hospitals, notified the Department under the last Administration that they had opted into the accommodation and expressed no objections to doing so. We also received public comments from organizations of similar nonprofit employers indicating that the accommodation satisfied their religious objections. These final rules leave the accommodation in place as an optional process. Thus, it is not clear to the Departments that all or most of such large nonprofit employers will choose to use the expanded exemption instead of the accommodation. If they continue to use the accommodation, their insurers or third party administrators would continue to be required to provide contraceptive coverage to the plan sponsors' employees through such accommodation.

Given the sincerely held religious beliefs of many nonprofit religious organizations, some commenters also contended that continuing to impose the contraceptive Mandate on certain nonprofit religious objectors might also undermine the Government's broader interests in ensuring health coverage by causing some entities to stop providing health coverage entirely.[59] Although the Departments do not know the extent to which that effect would result from not extending exemptions, we wish to avoid that potential obstacle to the general expansion of health coverage.

G. Closely Held For-Profit Entities (45 CFR 147.132(a)(1)(i)(C))

The previous regulations did not exempt plans sponsored by closely held for-profit entities; however, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(C), "[a] closely held for-profit entity." These rules finalize § 147.132(a)(1)(i)(C) without change.

Some commenters supported including these entities in the exemption, saying owners of such entities exercise their religious beliefs through their businesses and should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise religion or should not have their religious opposition to contraceptive coverage protected by the exemption. Some said the entities should not be able to impose their beliefs about contraceptive coverage on their employees, and that doing so constitutes discrimination.

As set forth in the Religious IFC, the Departments believe it is appropriate to expand the exemptions to include closely held for-profit employers in

[58] Notably, "the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.'" *Boy Scouts of America* v. *Dale*, 530 U.S. 640, 655 (2000).

[59] See, *e.g.*, Manya Brachear Pashman, "Wheaton College ends coverage amid fight against birth control mandate," Chicago Tribune, July 29, 2015; Laura Bassett, "Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate," HuffPost, May 15, 2012.

order to protect the religious exercise of those entities and their owners. The ACA did not apply the preventive services mandate to the many grandfathered health plans among closely held as well as publicly traded for-profit entities, encompassing tens of millions of women. As explained below, we are not aware of evidence showing that the expanded exemptions finalized here will impact such a large number of women. And, in the Departments' view, the decision by Congress to not apply the preventive services mandate to grandfathered plans did not constitute improper discrimination or an imposition of beliefs. We also do not believe RFRA or the large number of other statutory exemptions Congress has provided for religious beliefs (including those exercised for profit) in certain health contexts such as sterilization, contraception, or abortion have been improper.

Including closely held for-profit entities in the exemption is also consistent with the Supreme Court's ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization, and rejected the previous Administration's argument to the contrary. 134 S. Ct. at 2768–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby*.[60]

H. For-Profit Entities That Are Not Closely Held (45 CFR 147.132(a)(1)(i)(D))

The previous regulations did not exempt for-profit entities that are not closely held. However, the Religious IFC included in its list of exempt plan sponsors, at § 147.132(a)(1)(i)(D), "[a] for-profit entity that is not closely held." These rules finalize § 147.132(a)(1)(i)(D) without change.

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. Some commenters supported including such entities, including publicly traded businesses, in the scope of the exemption. Some of them said that publicly traded entities have historically taken various positions on important public concerns beyond merely (and exclusively) seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to exercise religious views against contraceptive coverage. They also said that other protections for religious beliefs in federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines "persons," protected under RFRA, to include corporations at 1 U.S.C. 1. Other commenters opposed including publicly traded companies in the expanded exemptions. Some of these commenters stated that such companies could not exercise religious beliefs, and opposed the effects on women if they could. These commenters also objected that including such employers, along with closely held businesses, would extend the exemptions to all or virtually all employers.

The Departments conclude it is appropriate to include entities that are not closely held within the expanded exemptions for entities with religious objection. RFRA prohibits the federal government from "substantially burden[ing] a person's exercise of religion . . . ." unless it demonstrates that the application of the burden to the person" is the least restrictive means to achieve a compelling governmental interest. 42 U.S.C. 2000bb–1(a) & (b). As commenters noted, the definition of "person" applicable in RFRA is found at 1 U.S.C. 1, which defines "person" as including "corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals." Accordingly, the Departments' decision to extend the religious exemption to publicly traded for profit corporations is supported by the text of RFRA. The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held religious beliefs, is a matter of well-established State law with respect to corporate decision-making,[61] and the Departments expect that application of such laws would cabin the scope of this exemption.

As to the impact of so extending the religious exemption, the Departments are not aware of any publicly traded entities that have publicly objected to providing contraceptive coverage on the basis of religious belief. As noted above, before the ACA, a substantial majority of employers covered contraceptives. Some commenters opposed to including publicly traded entities in these exemptions noted that there did not appear to be any known religiously motivated objections to the Mandate from publicly traded for-profit corporations. These comments support our estimates that including publicly traded entities in the exemptions will have little, if any effect, on contraceptive coverage for women. We likewise agree with the Supreme Court's statement in *Hobby Lobby* that it is unlikely that many publicly traded companies will adopt religious objections to offering women contraceptive coverage. *See* 134 S. Ct. at 2774. Some commenters contended that, because many closely held for-profit businesses expressed religious objections to the Mandate, or took advantage of the accommodation, it is likely that many publicly traded businesses will do so. The Departments agree it is possible that publicly traded businesses may use the expanded exemption. But while scores of closely held for-profit businesses filed suit against the Mandate, no publicly traded entities did so, even though they were not authorized to seek the accommodation. Based on these data points, we believe the impact of the extension of the exemption to publicly traded for-profit organizations will not be significant. Below, based on limited data, but on years of receiving public comments and defending litigation brought by organizations challenging the Mandate on the basis of their religious objections, our best estimate of the anticipated effects of these rules is that no publicly traded employers will invoke the religious exemption.

In the Departments' view, such estimate does not lead to the conclusion that the religious exemption should not be extended to publicly traded corporations. The Departments are generally aware that, in a country as large as the U.S., comprised of a supermajority of religious persons,[62] some publicly traded entities might claim a religious character for their company, or the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.[63] Thus we consider

[60] *See* Jennifer Haberkorn, "Two years later, few Hobby Lobby copycats emerge," *Politico* (Oct. 11, 2016), *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627.*

[61] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which the organization is incorporated or organized.

[62] For example, in 2017, 74 percent of Americans said that religion is fairly important or very important in their lives, and 87 percent of Americans said they believe in God. Gallup, "Religion," available at *https://news.gallup.com/poll/1690/religion.aspx.*

[63] *See, for example,* Kapitall, "4 Publicly Traded Religious Companies if You're Looking to Invest in

it possible that a publicly traded company might have religious objections to contraceptive coverage. Moreover, as noted, there are many closely held for-profit corporations that do have religious objections to covering some or all contraceptives. The Departments do not want to preclude such a closely held corporation from having to decide between relinquishing the exemption or financing future growth by sales of stock, which would be the effect of denying it the exemption if it changes its status and became a publicly traded entity. The Departments also find it relevant that other federal conscience statutes, such as those applying to hospitals or insurance companies, do not exclude publicly traded businesses from protection.[64] As a result, the Departments continue to consider it appropriate not to exclude such entities from these expanded exemptions.

I. Other Non-Governmental Employers (45 CFR 147.132(a)(1)(i)(E))

As noted above, the exemption in the previous regulations, found at § 147.131(a), included only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order. The Religious IFC included, in its list of exempt plan sponsors at § 147.132(a)(1)(i)(E), "[a]ny other non-governmental employer." These rules finalize § 147.132(a)(1)(i)(E) without change.

Some commenters objected to extending the exemption to other nongovernmental employers, asserting that it is not clear such employers should be protected, nor that they can assert religious objections. The Departments, however, agree with other commenters that supported that provision of the Religious IFC. The Departments believe it is appropriate that any nongovernmental employer asserting the requisite religious objections should be protected from the Mandate in the same way as other plan sponsors. Such other employers could include, for example, association health plans.[65] The reasons discussed above for providing the exemption to various specific kinds of employers, and for their ability to assert sincerely held religious beliefs using ordinary mechanisms of corporate decision-making, generally apply to other nongovernmental employers as well, if they have sincerely held religious beliefs opposed to contraceptive coverage and otherwise meet the requirements of these rules. We agree with commenters who contend there is not a sufficient basis to exclude other nongovernmental employers from the exemption.

J. Plans Established or Maintained by Objecting Nonprofit Entities (45 CFR 147.132(a)(1)(ii))

Based on the expressed intent in the Religious IFC, as discussed above, to expand the exemption to encompass plans established or maintained by nonprofit organizations with religious objections, and on public comments received concerning those exemptions, these rules finalize new language in § 147.132(a)(1)(ii) to better clarify the scope and application of the exemptions.

The preamble to the Religious IFC contained several discussions about the Departments' intent to exempt plans established or maintained by certain religious organizations that have the requisite objection to contraceptive coverage, including instances in which the plans encompass multiple employers. For example, as noted above, the Departments intended that the exemption for houses of worship and integrated auxiliaries be interpreted to apply on a plan basis, instead of on an employer-by-employer basis. In addition, the Departments discussed at length the fact that, under the prior regulations, where an entity was enrolled in a self-insured church plan exempt from ERISA under ERISA section 3(33) and the accommodation in the previous regulations was used, that accommodation process provided no mechanism to impose, or enforce, the accommodation requirement of contraceptive coverage against a third party administrator of such a plan. As a result, the prior accommodation served, in effect, as an exemption from requirements of contraceptive coverage for all organizations and employers covered under a self-insured church plan.

In response to these discussions in the Religious IFC, some commenters, including some church plans, supported the apparent intent to exempt such plans on a plan basis, but suggested that additional clarification is needed in the text of the rule to effect this intent. They observed that some plans are established or maintained by religious nonprofit entities that might not be houses of worship or integrated auxiliaries, and that some employers that adopt or participate in such plans may not be the "plan sponsors." They recommended, therefore, that the final rules specify that the exemption applies on a plan basis when plans are established or maintained by houses of worship, integrated auxiliaries, or religious nonprofits, so as to shield employers that adopt such plans from penalties for noncompliance with the Mandate.

The text of the prefatory language of § 147.132(a)(1), as set forth in the Religious IFC, declared that the Guidelines would not apply "with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization." We intended this language to exempt a plan and/or coverage where the entity that established or maintained a plan was an objecting organization, and not just to look at the views or status of individual employers (or other entities) participating in such plan. The Departments agree with commenters who stated that additional clarity is needed and appropriate in these final rules, in order to ensure that such plans are exempt on a plan basis, and that employers joining or adopting those plans are exempt by virtue of the plan itself being exempt. Doing so will make the application of the expanded exemption clearer, and protect employers (and other entities) participating in such plans from penalties for noncompliance with the Mandate. Clearer language will better realize the intent to exempt plans and coverage "established or maintained by an objecting organization," and make the operation of that exemption simpler by specifying that the exemption applies based on the objection of the entity that established or maintains the plan. Such language would also resolve the anomaly that, under the previous rules, only self-insured church plans (not insured church plans) under ERISA section 3(33) were, in effect, exempt—but only indirectly through the Departments' inability to impose, or enforce, the accommodation process against the third party administrators of such plans, instead of being specifically exempt in the rules.

We believe entities participating in plans established or maintained by an objecting organization usually share the views of those organizations. Multiple lawsuits were filed against the Departments by churches that established or maintained plans, or the church plans themselves, and they generally declared that the entities or individuals participating in their plans

Faith" (Feb. 7, 2014), *http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665.*

[64] *See, for example,* 42 U.S.C. 300a–7, 42 U.S.C. 238n, Consolidated Appropriations Act of 2018, Div. H, Sec. 507(d), Public Law 115–141, and *id.* at Div. E, Sec. 808.

[65] See 29 CFR 2510.3–5.

are usually required to share their religious affiliation or beliefs. In addition, because, as we have stated before, "providing payments for contraceptive services is cost neutral for issuers" (78 FR 39877), we do not believe this clarification would produce any financial incentive for entities that do not have religious objections to contraceptive coverage to enter into plans established or maintained by an organization that does have such objections.

Therefore, the Departments finalize the text of § 147.132(a)(1) of the Religious IFC with the following change: adding a provision that makes explicit this understanding, in a new paragraph at § 147.132(a)(1)(ii). This language now specifies that the exemptions encompassed by § 147.132(a)(1) include: "[a] group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan[.]"

K. Institutions of Higher Education (45 CFR 147.132(a)(1)(iii))

The previous regulations did not exempt student health plans arranged by institutions of higher education, although it did, for purposes of the accommodation, treat plans arranged by institutions of higher education similar to the way in which the regulations treated plans of nonprofit religious employers. *See* 80 FR at 41347. The Religious IFC included in its list of exemptions, at § 147.132(a)(1)(ii), "[a]n institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to 'plan participants and beneficiaries' will be interpreted as references to student enrollees and their covered dependents." These rules finalize this language with a change to clarify their application, as discussed below, and by redesignating the paragraph as § 147.132(a)(1)(iii).

These rules treat the plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. These rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.132(a)(1)(iii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held religious beliefs, to their arrangement of student health insurance coverage in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer.

Some commenters supported including, in the expanded exemptions, institutions of higher education that provide health coverage for students through student health plans but have religious objections to providing certain contraceptive coverage. They said that religious exemptions allow freedom for certain religious institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemptions would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result among those women.

In the Departments' view, the reasons for extending the exemptions to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. Only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities.[66] It is necessarily true that an even smaller number receive such coverage from religious schools, and from religious or other private schools that object to arranging contraceptive coverage. Religious institutions of higher education are private entities with religious missions. Various commenters asserted the importance, to many of those institutions, of being able to adhere to their religious tenets. Indeed, many students who attend such institutions do so because of the institutions' religious tenets. No student is required to attend such an institution. At a minimum, students who attend private colleges and universities have the ability to ask those institutions in advance what religious tenets they follow, including whether the institutions will provide contraceptives in insurance plans they arrange. Some students wish to receive contraceptive coverage from a health plan arranged by an institution of higher education. But other students wish to attend an institution of higher education that adheres to its religious mission about contraceptives in health insurance. And still other students favor contraception, but are willing to attend a religious university without forcing it to violate its beliefs about contraceptive coverage. Exempting religious institutions that object to contraceptive coverage still allows contraceptive coverage to be provided by institutions of higher education more broadly. The exemption simply makes it legal under federal law for institutions to adhere to religious beliefs that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, and makes it more possible for students to attend institutions of higher education that hold those views.

In addition, under the previous exemption and accommodation, it was possible for self-insured church plans exempt from ERISA that have religious objection to certain contraceptives to avoid any requirement that either they or their third party administrators provide contraceptive coverage. As seen

[66] The American College Health Association estimates that, in 2014, student health insurance plans at colleges and universities covered "more than two million college students nationwide." "Do You Know Why Student Health Insurance Matters?" available at *https://www.acha.org/documents/Networks/Coalitions/Why_SHIPs_Matter.pdf*. We assume for the purposes of this estimate that those plans covered 2,100,000 million students. Data from the Department of Education shows that in 2014, there were 20,207,000 students enrolled in degree-granting postsecondary institutions. National Center for Education Statistics, Table 105.20, "Enrollment in elementary, secondary, and degree-granting postsecondary institutions, by level and control of institution, enrollment level, and attendance status and sex of student: Selected years, fall 1990 through fall 2026," available at *https://nces.ed.gov/programs/digest/d16/tables/dt16_105.20.asp?current=yes*.

in some public comments and litigation statements, some such self-insured church plans provide health coverage for students at institutions of higher education covered by those church plans. In order to avoid the situation where some student health plans sponsored by institutions with religious objections are effectively exempt from the contraceptive Mandate, and other student health plans sponsored by other institutions with similar religious objections are required to comply with the Mandate, the Departments consider it appropriate to extend the exemption, so that religious colleges and universities with objections to the Mandate would not be treated differently in this regard.

The Departments also note that the ACA does not require institutions of higher education to provide student health insurance coverage. As a result, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student health insurance plans, rather than comply with the Mandate or be subject to the accommodation.[67] Extending the exemption in these rules removes an obstacle to such entities deciding to offer student health insurance plans, thereby giving students another health insurance option.

As noted above, it is not clear that studies discussing various effects of birth control access clearly and specifically demonstrate a negative impact to students in higher education because of the expanded exemption in these final rules. The Departments consider these expanded exemptions to be an appropriate and permissible policy choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these expanded exemptions.

Finally, the Religious IFC specified that the plan sponsor exemption applied to "non-governmental" plan sponsors (§ 147.132(a)(1)(i)), including "[a]ny other non-governmental employer" (§ 147.132(a)(1)(i)(E)). Then, in § 147.132(a)(1)(ii), the rule specified that the institution of higher education exemption applicable to the arrangement of student health insurance coverage applied "in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer." Consequently, the Religious IFC's expanded exemptions only applied to non-governmental institutions of higher education, including for student health insurance coverage, not to governmental institutions of higher education. Nevertheless, the term "non-governmental," while appearing twice in § 147.132(a)(1)(i) concerning plan sponsors, was not repeated in in § 147.132(a)(1)(ii). To more clearly specify that this limitation was intended to apply to § 147.132(a)(1)(ii), we finalize this paragraph with a change by adding the phrase "which is non-governmental" after the phrase "An institution of higher education as defined in 20 U.S.C. 1002".

L. Health Insurance Issuers (45 CFR 147.132(a)(1)(iv))

The previous regulations did not exempt health insurance issuers. However, the Religious IFC included in its list of exemptions at § 147.132(a)(1)(iii), "[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]" These rules finalize this exemption with technical changes to clarify the language based on public comments, and redesignate the paragraph as § 147.132(a)(1)(iv).

The Religious IFC extends the exemption to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services. Under this exemption, the only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on their objection. An exempt issuer can then offer an exempt health insurance product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless it is also exempt from that requirement.

Under these rules, issuers that hold their own objections, based on sincerely held religious beliefs, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their religious beliefs, or on their moral convictions under the companion final rules published elsewhere in today's **Federal Register**. Likewise, issuers with sincerely held moral convictions, that are exempt under those companion final rules, could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments provided a similar exemption for issuers in the context of moral objections, but we used slightly different operative language. There, in the second sentence, instead of saying "the plan remains subject to any requirement to provide coverage for contraceptive services," the exemption stated, "the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services." Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. Consequently, these rules finalize the issuer exemption paragraph from the Religious IFC with minor technical changes so that the final language will mirror language from the Moral IFC, stating that the exemption encompasses: "[a] health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iv) of this section, the group health plan established or maintained by the plan sponsor with

[67] See, *e.g.*, Manya Brachear Pashman, "Wheaton College ends coverage amid fight against birth control mandate," Chicago Tribune, July 29, 2015; Laura Bassett, "Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate," HuffPost, May 15, 2012.

which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement[.]"

Some commenters supported including this exemption for issuers in these rules, both to protect the religious exercise of issuers, and so that in the future religious issuers that may wish to specifically serve religious plan sponsors would be free to organize. Other commenters objected to including an exemption for issuers. Some objected that issuers cannot exercise religious beliefs, while others objected that exempting issuers would threaten contraceptive coverage for women. Some commenters said that it was arbitrary and capricious for the Departments to provide an exemption for issuers if we do not know that issuers with qualifying religious objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage. The issuer exemption therefore serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors and plans that independently qualify for an exemption, will remove a possible obstacle to religious issuers being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers from being required to issue policies that cover contraception in violation of the issuers' sincerely held religious beliefs, and from being required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise religious beliefs. First, since RFRA protects the religious exercise of corporations as persons, the religious exercise of health insurance issuers—which are generally organized as corporations—is protected by RFRA. In addition, many federal health care conscience laws and regulations specifically protect issuers or plans. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment specifically protects, among other entities, provider-sponsored organizations, health maintenance organizations (HMOs), health insurance plans, and "any other kind of health care facilit[ies], organization[s], or plan[s]" as a "health care entity" from being required to pay for, or provide coverage of, abortions. *See for example,* Consolidated Appropriations Act of 2018, Public Law 115–141, Div. H, Sec. 507(d), 132 Stat. 348, 764 (Mar. 23, 2018).[68] Congress also declared this year that "it is the intent of Congress" to include a "conscience clause" which provides exceptions for religious beliefs if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans." *See id.* at Div. E, Sec. 808, 132 Stat. at 603. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments' understanding that third party administrators are not typically designated as plan administrators, and, therefore, would not normally act as plan administrators, under section 3(16) of ERISA. Therefore, to the Departments' knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or decline to continue, contracts as third party administrators of such plans.

M. Description of the Religious Objection (45 CFR 147.132(a)(2))

The previous regulations did not specify what, if any, religious objection applied to its exemption; however, the Religious IFC set forth the scope of the religious objection of objecting entities in § 147.132(a)(2), as follows: "The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs." These rules finalize this description with technical changes to clarify the scope of the objection as intended in the Religious IFC, and based on public comments.

Throughout the exemptions for objecting entities, the rules specify that they apply where the entities object as specified in § 147.132(a)(2) of the Religious IFC. That paragraph describes the religious objection by specifying that exemptions for objecting entities will apply to the extent that an entity described in paragraph (a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

[68] ACA section 1553 protects an identically defined group of "health care entities," including provider-sponsored organizations, HMOs, health insurance plans, and "any other kind of . . . plan," from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(a)(2), provided a similar description of the scope of the objection based on moral convictions rather than religious beliefs, but we used slightly different operative language. There, instead of saying the entity "objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services," the paragraph stated the entity "objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments." Some commenters took note of this difference, and asked the Departments to clarify which language applies, and whether the Departments intended any difference in the operation of the two paragraphs. The Departments did not intend the language to operate differently. The language in the Moral IFC accurately, and more clearly, expresses the intent set forth in the Religious IFC about how the issuer exemption applies. The Religious IFC explained that the intent of the expanded exemptions was to encompass entities that objected to providing or arranging for contraceptive coverage in their plans, and to encompass entities that objected to the previous accommodation process, by which their issuers or third party administrators were required to provide contraceptive coverage or payments in connection with their plans. In other words, an entity would be exempt from the Mandate if it objected to complying with the Mandate, or if it objected to complying with the accommodation. The language in the Religious IFC encompassed both circumstances by encompassing an objection to providing "coverage [or] payments" for contraceptive services, and by encompassing an objection to "a plan that provides" coverage or payments for contraceptive services. But the language describing the objection set forth in the Moral IFC does so more clearly, and restructuring the sentence could make it clearer still. Questions by commenters about the scope of the description suggests that we should restructure the description, in a non-substantive way, to provide more clarity. The Departments do this by breaking some of the text out into subparagraphs, and rearranging clauses so that it is clearer which words they modify. The new structure specifies that it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) coverage or payments for contraceptive services, and it includes an objection to establishing, maintaining, providing, offering, or arranging for (as applicable) a plan, issuer, or third party administrator that provides contraceptive coverage. This more clearly encompasses objections to complying with either the Mandate or the accommodation. Consequently, these rules finalize the paragraph describing the religious objection in the Religious IFC with minor technical changes so that the final language will essentially mirror language from the Moral IFC. The introductory phrase of the religious objection set forth in paragraph (a)(2) is finalized to state the exemption "will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable)". The remainder of the paragraph is broken into two sub-paragraphs, regarding either "coverage or payments for some or all contraceptive services," or "a plan, issuer, or third party administrator that provides or arranges such coverage or payments."

Some commenters observed that by allowing exempt groups to object to "some or all" contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators. The Departments have concluded, however, that, just as the exemption under the previous regulations allowed entities to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. Notably, even where an entity or individual qualifies for an exemption under these rules, these rules do not require the issuer or third party administrator to contract with that entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual variation of a plan. These rules simply remove the federal Mandate that, in some cases, could have led to penalties for an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying religious objection. Similarly, under the previous exemption, the plans of houses of worship and integrated auxiliaries were exempt from offering some or all contraceptives, but the previous regulations did not require issuers and third party administrators to contract with those exempt entities if they chose not to do so.

N. Individuals (45 CFR 147.132(b))

The previous regulations did not provide an exemption for objecting individuals. However, the Religious IFC expanded the exemptions to encompass objecting individuals (referred to here as the "individual exemption"), at § 147.132(b). These rules finalize the individual exemption from the Religious IFC with changes, which reflect both non-substantial technical revisions, and changes based on public comments to more clearly express the intent of the Religious IFC.

In the separate companion IFC to the Religious IFC—the Moral IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Religious IFC described what may be offered to objecting individuals as "a separate benefit package option, or a separate policy, certificate or contract of insurance," the Moral IFC said a willing issuer and plan sponsor may offer "a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects" under the individual exemption. Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of "a separate group health plan," as set forth in the version found in § 147.133(b), because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee's objection. Consequently, these rules finalize the individual

exemption by making a technical change to the language to adopt the formulation, "a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects" under the individual exemption.

Some commenters supported the individual exemption as providing appropriate protections for the religious beliefs of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to contraceptive coverage but is willing (and, as applicable, the issuer is also willing) to provide coverage that is consistent with an individual's religious objections. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage. Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. As discussed in the Religious IFC, the individual exemption only operates in the case where the group health plan sponsor or group or individual market health insurance issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases.

In addition, Congress has provided several protections for individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. *See for example*, Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–141, 132 Stat. 348, 593–94 (Mar. 23, 2018). While some commenters proposed to construe this provision narrowly, Congress likewise provided that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions". *Id.* at Div. E, Sec. 808, 132 Stat. at 603. A religious exemption for individuals would not be effective if the government simultaneously made it illegal for issuers and group health plans to provide individuals with policies that comply with the individual's religious beliefs.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers.

By its terms, the individual exemption would also apply with respect to individuals in plans arranged by institutions of higher education, if the issuers offering those plans were willing to provide plans complying with the individuals' objections. Because federal law does not require institutions of higher education to arrange such plans, the institutions would not be required by these rules to arrange a plan compliant with an individual's objection if the institution did not wish to do so.

As an example, in one lawsuit brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees' religious beliefs, or against the individual employees who accept such offers. *See Wieland*, 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these final rules do not affect such other laws or terms.

Some individuals commented that they welcomed the individual exemption so that their religious beliefs were not forced to be in tension with their desire for health coverage. The Departments believe the individual exemption may help to meet the ACA's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.[69] At the same time, this individual exemption "does not undermine the governmental interests furthered by the contraceptive

[69] See also, for example, *Wieland*, 196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to "forgo health insurance altogether."

coverage requirement,'' [70] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives. Other commenters expressed concern that there might be multiple variations in the kinds of contraceptive coverage to which individuals object, and this might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the religious beliefs of an exempt individual. As discussed above, where the individual exemption applies, it only affects the coverage of an individual. If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons they can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Religious IFC implied this conclusion, by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, this was different than the language applicable to the exemptions under § 147.132(a), which specifies that the exemptions apply ''to the extent'' of the religious objections, so that, as discussed above, the exemptions include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b) with the following change, by adding the following sentence at the end of the paragraph: ''Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the individual with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.''

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held religious beliefs objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to this employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under a policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with clarifying changes to reflect the Departments' intent.

O. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations set forth an accommodation process at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, as an alternative method of compliance with the Mandate. Under the accommodation, if a religious nonprofit entity, or a religious closely held for-profit business, objected to coverage of some or all contraceptive services in its health plan, it could file a notice or fill out a form expressing this objection and describing its objection to its plan and issuer or third party administrator. Upon doing so, the plan would not cover some or all contraceptive services, and the issuer or third party administrator would be responsible for providing or arranging for persons covered by the plan to receive coverage or payments of those services (except in the case of self-insured church plans exempt from ERISA, in which case no such obligation was imposed on the third party administrator). The accommodation was set forth in regulations of each of the Departments. Based on each Department's regulatory authority, HHS regulations applied to insured group health plans, and DOL and Treasury regulations applied to both insured group health plans and self-insured group health plans.

The Religious IFC maintained the accommodation process. Nevertheless, by virtue of expanding the exemptions to encompass all entities that were eligible for the accommodation process under the previous regulations, in addition to other newly exempt entities, the Religious IFC rendered the accommodation process optional. Entities could choose not just between the Mandate and the accommodation, but between the Mandate, the exemption, and the accommodation. These rules finalize the optional accommodation process and its location in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A, but the Departments do so with several changes based on public comments.

Many commenters supported keeping the accommodation as an optional process, including some commenters who otherwise supported creating the expanded exemptions. Some commenters opposed making the accommodation optional, but asked the Departments to return to the previous regulations in which entities that did not meet the narrower exemption could only choose between the accommodation process or direct compliance with the Mandate. Some commenters believed there should be no exemptions and no accommodation process.

The Departments continue to consider it appropriate to make the accommodation process optional for entities that are otherwise also eligible for the expanded exemptions—that is, to keep it in place as an option that exempt entities can choose. The accommodation provides contraceptive access, which is a result many opponents of the expanded exemptions said they desire. The accommodation involves some regulation of issuers and third party administrators, but the previous

[70] 78 FR 39874.

regulations had already put that regulatory structure in place. These rules for the most part merely keep it in place and maintain the way it operates. The Religious IFC adds some additional paperwork burdens as a result of the new interaction between the accommodation and the expanded exemptions; those are discussed below.

Above, the Departments discussed public comments concerning whether we should have merely expanded the accommodation rather than expanding the exemptions. The Religious IFC and these final rules expand the kinds of entities that may use the optional accommodation, by expanding the exemptions and allowing any exempt entities to opt to make use of the accommodation. Consequently, under these rules, objecting employers may make use of the exemption or may choose to utilize the optional accommodation process. If an eligible organization uses the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

Some commenters asked that these final rules create an alternative payment mechanism to cover contraceptive services for third party administrators obligated to provide or arrange such coverage under the accommodation. These rules do not concern the payment mechanism, which is set forth in separate rules at 45 CFR 156.50. The Departments do not view an alternative payment mechanism as necessary. As discussed below, although the Departments do not know how many entities will use the accommodation, it is reasonably likely that some entities previously using it will continue to do so, while others will choose the expanded exemption, leading to an overall reduction in the use of the accommodation. The Departments have reason to believe that these final rules will not lead to a significant expansion of entities using the accommodation, since nearly all of the entities of which the Departments are aware that may be interested in doing so were already able to do so prior to the Religious IFC. Moreover, it is still the case under these rules that if an entity serving as a third party administrator does not wish to satisfy the obligations it would need to satisfy under an accommodation, it could choose not to contract with an entity that opts into the accommodation. This conflict is even less likely now that entities eligible for the accommodation are also eligible for the exemption. For these reasons, the Departments do not find it necessary to add an additional payment mechanism for the accommodation process.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these rules, and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation. Some commenters suggested HHS has not yet issued guidance on the revocation process, but CCIIO provided guidance concerning this process on November 30, 2017.[71] These rules supersede that guidance, and adopt or modify its specific guidelines as explained below. As a result, these rules delete references, set forth in the Religious IFC's accommodation regulations, to "guidance issued by the Secretary of the Department of Health and Human Services."

The guidance stated that an entity that was using the accommodation under the previous rules, or an entity that adopts the accommodation maintained by the IFCs, could revoke its use of the accommodation and use the exemption. This guideline applies under the final rules. This revocation process applies both prospectively to eligible organizations that decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that invoked the accommodation prior to the effective date of the Religious IFC either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies.

The guidance stated that, when the accommodation is revoked by an entity using the exemption, the issuer of the eligible organization must provide participants and beneficiaries written notice of such revocation. These rules adopt that guideline. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. The guidance further stated that the notice may be provided by the organization itself, its group health plan, or its third party administrator, as applicable. The guidance stated that, under the regulation at 45 CFR 147.200(b), "[t]he notice of modification must be provided in a form that is consistent with the rules of paragraph (a)(4) of this section," and (a)(4) has detailed rules on when electronic notice is permitted. These guidelines still apply under the final rules. These rules adopt those guidelines.

The guidance further specified that the revocation of the accommodation would be effective notice on the first day of the first plan year that begins on or after 30 days after the date of the revocation, or alternatively, whether or not the objecting entity's group health plan or issuer listed the contraceptive benefit in its Summary of Benefits of Coverage (SBC), the group health plan or issuer could revoke the accommodation by giving at least 60-days prior notice pursuant to section 2715(d)(4) of the PHS Act (incorporated into ERISA and the Code)[72] and applicable regulations thereunder to revoke the accommodation. The guidance noted that, unlike the SBC notification process, which can effectuate a modification of benefits in the middle of a plan year, provided it is allowed by State law and the contract of the policy, the 30 day notification process under the guidance can only effectuate a benefit modification at the beginning of a plan year. This part of the guidance is adopted in part and changed in part by these final rules, as follows, based on public comments on the issue.

Some commenters asked that revocations only be permitted to occur on the first day of the next plan year, or no sooner than January 2019, to avoid burdens on plans and because some states do not allow for mid-year plan changes. The Departments believe that providing 60-days notice pursuant to section 2715(d)(4) of the PHS Act, where applicable, is a mechanism that already exists for making changes in health benefits covered by a group health plan during a plan year; that process already takes into consideration any applicable state laws. However, in response to public comments, these rules change the accommodation provisions from the Religious IFC to indicate that, as a transitional rule, providing 60-days notice for revoking an accommodation is only available, if applicable, to plans that are using the accommodation at the time of the

[71] *See* Randy Pate, "Notice by Issuer or Third Party Administrator for Employer/Plan Sponsor of Revocation of the Accommodation for Certain Preventive Services," CMS (Nov. 30, 2017), *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf.*

[72] *See also* 26 CFR 54.9815–2715(b); 29 CFR 2590.715–2715(b); 45 CFR 147.200(b).

publication of these final rules. As a general rule, for plans that use the accommodation in future plan years, the Departments believe it is appropriate to allow revocation of an accommodation only on the first day of the next plan year. Based on the objections of various litigants and public commenters, we believe that some entities already using the accommodation may have been doing so only because previous regulations denied them an exemption. For them, access to the transitional 60-days notice procedure (if applicable) is appropriate in the period immediately following the finalization of these rules. In future plan years, however—plan years that begin after the effective date of these final rules—plans and entities that qualify as exempt under these rules will have been on notice that they qualify for an exemption or the accommodation. If they have opted to enter or remain in the accommodation in those future plan years, when they could have chosen the exemption, the Departments believe it is appropriate for them to wait until the first day of the following plan year to change to exempt status.[73]

This change is implemented in the following manner. In the Religious IFC, the accommodation provisions addressing revocation were found at 45 CFR 147.131(c)(4), 26 CFR 54.9815–2713AT(a)(5),[74] and 29 CFR 2590.715–2713A(a)(5).

The provisions in the Religious IFC (with technical variations among the HHS, Labor, and Treasury rules) state that a written notice of revocation must be provided "as specified in guidance issued by the Secretary of the Department of Health and Human Services." On November 30, 2017, HHS issued the guidance regarding revocation. These final rules incorporate this guidance, with certain clarifications, and state that the revocation notice must be provided "as specified herein." The final rule incorporates the two sets of directions for revoking the accommodation initially set forth in the interim guidance in the following manner. The first, designated as subparagprah (1) as a "[t]ransitional rule," explains that if contraceptive coverage is being offered through the accommodation process on the date on which these final rules go into effect, 60-days notice may be provided to revoke the accommodation process, or they revocation may occur "on the first day of the first plan year that begins on or after 30 days after the date of the revocation" consistent with PHS Act section 2715(d)(4), 45 CFR 147.200(b), 26 CFR 54.9815–2715(b), or 29 CFR 2590.715–2715(b). The second direction, set forth in subparagraph (ii), explains the "[g]eneral rule" that, in plan years beginning after the date on which these final rules go into effect, revocation of the accommodation will be effective on "the first day of the first plan year that begins on or after 30 days after the date of the revocation."

The Religious IFC states that if an accommodated entity objects to some, but not all, contraceptives, an issuer for an insured group health plan that covers contraceptives under the accommodation may, at the issuer's option, choose to provide coverage or payments for all contraceptive services, instead of just for the narrower set of contraceptive services to which the entities object. Some commenters supported this provision, saying that it allows flexibility for issuers that might otherwise face unintended burdens from providing coverage under the accommodation for entities that object to only some contraceptive items. The Departments have maintained this provision in these final rules. Note that this provision is consistent with the other assertions in the rules saying that an entity's objection applies "to the extent" of the entity's religious beliefs, because in this instance, under the accommodation, the plan participant or beneficiary still receives coverage or payments for all contraceptives, and this provision simply allows issuers more flexibility in choosing how to help provide that coverage.

Some commenters asked that the Departments retain the "reliance" provision, contained in the previous accommodation regulations, under which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. The Departments omitted this provision from the Religious IFC, on the grounds that this provision was less necessary where any organization eligible for the optional accommodation is also exempt. Nevertheless, in order to respond to concerns in public comments, and to prevent any risk to issuers of a mistake or misrepresentation by an organization seeking the accommodation process, the Departments have finalized the Religious IFC with an additional change that restores this clause. The clause uses the same language that was in the regulations prior to the Religious IFC, and it is inserted at 45 CFR 147.131(f), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e). As a result, these rules renumber the subsequent paragraphs in each of those sections.

P. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under "Contraceptive methods and counseling," "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." The previous regulations concerning the exemption and the accommodation used the terms contraceptive services and contraceptive coverage as catch-all terms to encompass all of those Guidelines' requirements. The 2016 update to the Guidelines are similarly worded. Under "Contraception," they include the "full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration." "instruction in fertility awareness-based methods," and "[c]ontraceptive care" to "include contraceptive counseling, initiation of contraceptive use, and follow-up care (for example, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method)."[75]

To more explicitly state that the exemption encompasses any of the contraceptive or sterilization services, items, or information that have been required under the Guidelines, the Religious IFC included a definition at 45

[73] These final rules go into effect 60 days after they are published in the **Federal Register**. Some entities currently using the accommodation may have a plan year that begins less than 30 days after the effective date of these final rules. In such cases, they may be unable, after the effective date of these final rules, to provide a revocation notice 30 days prior to the start of their next plan year. However, these final rules will be published at least 60 days prior to the start of that plan year. Therefore, entities exempt under these final rules that have been subject to the accommodation on the date these final rules are published, that wish to revoke the accommodation, and whose next plan years start after these final rules go into effect, but less than 30 days thereafter, may submit their 30 day revocation notices after these final rules are published, before these final rules are in effect, so that they will have submitted the revocation at least 30 days before their next plan year starts. In such cases, even though the revocation notice will be submitted before these final rules are in effect, the actual revocation will not occur until after these final rules are in effect, and plan participants will have been provided with 30 days' notice of the revocation.

[74] The Department of the Treasury's rule addressing the accommodation is being finalized at 26 CFR 54.9815–2713A, superseding its temporary regulation at 26 CFR 54.9815–2713AT.

[75] *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713AT(e), and 29 CFR 2590.715–2713A(e). These rules finalize those definitions without change, but renumber them as 45 CFR 147.131(f) and 147.132(c), 26 CFR 54.9815–2713A(e), and 29 CFR 2590.715–2713A(e), respectively.

Q. Severability

The Departments finalize without change (except for certain paragraph redesignations), the severability clauses in the interim final rules, namely, at paragraph (g) of 26 CFR 54.9815–2713A, the redesignated paragraph (g) of 29 CFR 2590.715–2713A, and 45 CFR 147.132(d).

R. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to "preventive" care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to "preventive" services or care.[76] The requirement in the Guidelines concerning "contraception" specifies several times that it encompasses "contraceptives," that is, medical products, methods, and services applied for "contraceptive" uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage, without cost-sharing, of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[77] The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans' decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use, or for another use. Section 2713(a)(4), however, draws a distinction between preventive care and screenings and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of contraceptive methods or care unless such methods or care is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules also do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply to the extent the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that under section 2713(a)(4), exempt organizations must provide coverage for drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the expanded exemptions could take contraceptive coverage away from many or most women. Still others opposed expanding the exemptions and contended that accurately determining the number of women affected by the expanded exemptions is not possible.

After reviewing the public comments, the Departments agree with commenters who said that estimating the impact of these final rules is difficult based on the limited data available to us, and with commenters who agreed with the Religious IFC that the expanded exemptions are likely to affect only a small percentage of women. The Departments do not find the estimates of large impacts submitted by some commenters more reliable than the estimates set forth in the Religious and Moral IFCs. Even certain commenters that "strongly oppos[ed]" the Religious IFC commented that merely "thousands" would be impacted, a number consistent with the Departments' estimate of the number of women who may be affected by the rule. The Departments' estimates of the impact of these final rules are discussed in more detail in the following section. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious IFC are still the best estimates available. Our estimates are discussed in more detail in the following section.

3. Interaction With State Laws

Some commenters asked the Departments to discuss the interaction between these final rules and state laws that either require contraceptive

[76] *Id.*

[77] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that "there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy." 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act 2713(a)(4) or the Guidelines require coverage of "contraceptive" methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead, it was an observation that such drugs—generally referred to as "contraceptives"—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the reference prior to the Religious IFC to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage for contraceptive use. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

coverage or provide religious exemptions from those and other requirements. Some commenters argued that providing expanded exemptions in these rules would negate state contraceptive requirements or narrower state religious exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage. The Department agrees that these rules concern only the applicability of the Federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state religious exemptions. If a plan is exempt under the Religious IFC and these rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the religious exemptions to declare that the Federal contraceptive Mandate will still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.[78]

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1). These rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with religious objections to cover contraceptives.

[78] Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the Federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. Elsewhere in this preamble, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

IV. Economic Impact and Paperwork Burden

The Departments have examined the impacts of the Religious IFC and the final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an "economically significant" regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding their anticipated effects, the Religious IFC and these rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of "economically significant" under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These final rules adopt as final and further change the amendments made by the Religious IFC, which amended the Departments' July 2015 final regulations. The Religious IFC and these final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held religious beliefs, and they revise the accommodation process to make it optional for eligible organizations. The expanded exemption applies to certain individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action has been taken, among other reasons discussed above, to provide for participation in the health insurance market by certain entities or individuals, by freeing them from penalties they could incur if they follow their sincerely held religious beliefs against contraceptive coverage.

2. Anticipated Effects

a. Removal of Burdens on Religious Exercise

Regarding entities and individuals that are extended an exemption by the Religious IFC and these final rules, without that exemption the Guidelines would require many of them to either pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which

some entities also believe entangles them in the provision of such objectionable coverage; or pay tax penalties, or be subject to other adverse consequences, for non-compliance with these requirements. These final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections to, and exempting them on the basis of such objections from, the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

b. Notices When Revoking Accommodated Status

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption, a notice will need to be sent to enrollees (either by the objecting entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during the current plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of the entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be $302,036.

c. Impacts on Third Party Administrators and Issuers

The Departments estimate that these final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their new exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation to which they were not previously provided access. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations for serving the fewer number of entities that will now opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation. While these rules make it legal for issuers to offer insurance coverage that omits contraceptives to exempt entities and individuals, these final rules do not require issuers to do so.

The Departments anticipate that the effect of these rules on adjustments made to the federally facilitated Exchange user fees under 45 CFR 156.50 will be that fewer overall adjustments will be made using the accommodation process, because there will be more entities who previously were reluctant users of the accommodation that will choose to operate under the newly expanded exemption than there will be entities not previously eligible to use the accommodation that will opt into it. The Departments' estimates of each number of those entities is set forth in more detail below.

d. Impacts on Persons Covered by Newly Exempt Plans

These final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. As discussed in the Religious IFC, the Departments did not have sufficient data on a variety of relevant factors to precisely estimate how many women would be impacted by the expanded exemptions or any related costs they may incur for contraceptive coverage or the results associated with any unintended pregnancies.

i. Unknown Factors Concerning Impact on Persons in Newly Exempt Plans

As referenced above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- How many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- Which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby*, several objecting entities have still provided coverage for 14 of the 18 FDA-approved women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- How many women will be covered by plans of entities using their newly exempt status.
- Which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- Whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- The degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- The degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- The degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- The extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

ii. Public Comments Concerning Estimates in Religious IFC

In the public comments, some commenters agreed with the Departments' estimate that, at most, the economic impact would lead to a potential transfer cost, from employers (or other plan sponsors) to affected women, of $63.8 million. Some commenters said the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women.

These general comments do not, however, substantially assist us in

estimating how many women would be affected by these expanded exemptions specifically, or among them, how many unintended pregnancies would result, or how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the transfer costs the Departments estimate, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives. The Departments conclude, therefore, that our estimates of the anticipated effect in the Religious IFC are still the best estimates we have based on the limited data available to make those estimates. We do not believe that the higher estimates submitted by various public commenters sufficiently took into consideration, or analyzed, the various factors that suggest the small percentage of entities that will now use the expanded exemptions out of the large number of entities subject to the Mandate overall. Instead, the Departments agree with various public commenters providing comment and analysis that, for a variety of reasons, the best estimate of the impact of the expanded exemptions finalized in these rules is that most women receiving contraceptive coverage under the Mandate will not be affected. We agree with such commenters that the number of women covered by entities likely to make use of the expanded exemptions in these rules is likely to be very small in comparison to the overall number of women receiving contraceptive coverage as a result of the Mandate.

iii. Possible Sources of Information for Estimating Impact

The Departments have access to the following general sources of information that are relevant to this issue, but these sources do not provide a full picture of the impact of these final rules. First, the regulations prior to the Religious IFC already exempted certain houses of worship and their integrated auxiliaries and, as explained elsewhere, effectively did not apply contraceptive coverage requirements to various entities in self-insured church plans. The effect of those previous exemptions or limitations are not included as effects of these rules, which leave those impacts in place. Second, in the Departments' previous regulations creating or expanding exemptions and the accommodation process we concluded that no significant burden or costs would result. 76 FR 46625; 78 FR 39889. Third, some entities, including some for-profit entities, object to only some but not all contraceptives, and in some cases will cover 14 of 18 FDA-approved women's contraceptive and sterilization methods.[79] *See Hobby Lobby*, 134 S. Ct. at 2766. The effects of the expanded exemptions will be mitigated to that extent. No publicly traded for-profit entities sued challenging the Mandate, and the public comments did not reveal any that specifically would seek to use the expanded exemptions. Consequently, the Departments agree with the estimate from the Religious IFC that publicly traded companies would not likely make use of these expanded exemptions.

Fourth, HHS previously estimated that 209 entities would make use of the accommodation process. To arrive at this number, the Departments used, as a placeholder, the approximately 122 nonprofit entities that brought litigation challenging the accommodation process, and the approximately 87 closely held for-profit entities that filed suit challenging the Mandate in general. The Departments' records indicate, as noted in the Religious IFC, that approximately 63 entities affirmatively submitted notices to HHS to use the accommodation,[80] and approximately 60 plans took advantage of the contraceptive user fees adjustments, in the 2015 plan year, to obtain reimbursement for contraceptive service payments made for coverage of such services for women covered by self-insured plans that were accommodated. Overall, while recognizing the limited data available, the Departments assumed that, under an expanded exemption and accommodation, approximately 109 previously accommodated entities would use an expanded exemption, and about 100 would continue their accommodated status. We also estimated that another 9 entities would use the accommodation where the entities were not previously eligible to do so.

These sources of information were outlined in the Religious IFC. Some commenters agreed with the Departments' estimates based on those sources, and while others disagreed, the Departments conclude that commenters did not provide information that allows us to make better estimates.

iv. Estimates Based on Litigating Entities That May Use Expanded Exemptions

Based on these and other factors, the Departments considered two approaches in the Religious IFC to estimate the number of women affected among entities using the expanded exemptions. First, following the use in previous regulations of litigating entities to estimate the effect of the exemption and accommodation, the Departments attempted to estimate the number of women covered by plans of litigating entities that could be affected by expanded exemptions. Based on papers filed in litigation, and public sources, the Departments estimated in the Religious IFC that approximately 8,700 women of childbearing age could have their contraception costs affected by plans of litigating entities using these expanded exemptions. The Departments believe that number is lower based upon the receipt, by many of those litigating entities, of permanent injunctions against the enforcement of section 2713(a)(4) to the extent it supports a contraceptive Mandate, which have been entered by federal district courts since the issuance of the Religious IFC.[81] As a result, these final rules will not affect whether such entities will be subject to the contraceptive Mandate. Subtracting those entities from the total, the Departments estimate that the remaining litigating entities employ

[79] By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, *https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf*. Hobby Lobby and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin: emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). *See* 134 S. Ct. at 2765–66. Hobby Lobby was willing to cover: sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives ("the Pill"—combined pill); oral contraceptives ("the Pill"—extended/continuous use/combined pill); oral contraceptives ("the Mini Pill"—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that Hobby Lobby and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and "[t]he pill and female sterilization have been the two most commonly used methods since 1982." *See* Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states*.

[80] This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. In addition, the Departments have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or the Departments were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage.

[81] *See, for example, Catholic Benefits Ass'n LCA* v. *Hargan*, No. 5:14–cv–00240–R (W.D. Okla. order filed Mar. 7, 2018), and *Dordt Coll.* v. *Burwell*, No. 5:13–cv–04100 (N.D. Iowa order filed June 12, 2018).

approximately 49,000 persons, male and female. The average percent of workers at firms offering health benefits that are actually covered by those benefits is 60 percent.[82] This amounts to approximately 29,000 employees covered under those plans. EBSA estimates that for each employee policyholder, there is approximately one dependent.[83] This amounts to approximately 58,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15 to 44—compose 20.2 percent of the general population.[84] Furthermore, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.[85] Therefore, the Departments estimate that approximately 5,200 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that might be affected by these final rules. The Departments also estimate that, for the educational institutions that brought litigation challenges objecting to the Mandate as applied to student coverage that they arranged—where (1) the institutions were not exempt under the prior rule, (2) their student plans were not self-insured, and (3) they have not received permanent injunctions preventing the application of the previous regulations—such student plans likely covered approximately 2,600 students. Thus, the Departments estimate the female members of those plans is 2,600 women.[86] Assuming, as referenced above, that 43.6 percent of such women use contraception covered by the Guidelines, the Departments estimate that 1,150 of those women would be affected by these final rules.

Together, this leads the Departments to estimate that approximately 6,400 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted previously, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do the Departments know how many would have alternative contraceptive access from a parent's or spouse's plan, or from federal, state, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

v. Estimates of Accommodated Entities That May Use Expanded Exemptions

In the Religious IFC, the Departments also examined data concerning user-fee reductions to estimate how many women might be affected by entities that are using the accommodation and would use the expanded exemptions under these final rules. Under the accommodation, HHS has received information from issuers that seek user fees adjustments under 45 CFR 156.50(d)(3)(ii), for providing contraceptive payments for self-insured plans that make use of the accommodation. HHS receives requests for fees adjustments both where Third Party Administrators (TPAs) for those self-insured accommodated plans are themselves issuers, and where the TPAs use separate issuers to provide the payments and those issuers seek fees adjustments. Where the issuers seeking adjustments are separate from the TPAs, the TPAs are asked to report the number of persons covered by those plans. Some users do not enter all the requested data, and not all the data for the 2017 plan year is complete. Nevertheless, HHS has reviewed the user fees adjustment data received for the 2017 plan year. HHS's best estimate from the data is that there were $38.4 million in contraception claims sought as the basis for user fees adjustments for plans, and that these claims were for plans covering approximately 1,823,000 plan participants and beneficiaries of all ages, male and female.

This number fluctuates from year to year. It is larger than the estimate used in the Religious IFC because, on closer examination of the data, this number better accounts for plans where TPAs were also issuers seeking user fees adjustments, in addition to plans where the TPA is separate from the issuer seeking user fees adjustments. The number of employers using the accommodation where user fees adjustments were sought cannot be determined from HHS data, because not all users are required to submit that information, and HHS does not necessarily receive information about fully insured plans using the accommodation. Therefore, the Departments still consider our previous estimate of 209 entities using the accommodation as the best estimate available.

As noted in the Religious IFC, HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly tens of thousands of persons each and are proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

The Departments continue to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.[87]

[82] See Kaiser Family Foundation and Health Research and Educational Trust, "Employer Health Benefits: 2018 Annual Survey" at 62, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018.*

[83] Employee Benefits Security Administration, "Health Insurance Coverage Bulletin" Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[84] United States Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." *https://www.hrsa.gov/womensguidelines/:* also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/*contraceptive-use-united-states.

[85] See *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states* (reporting that of 61,491,766 women aged 15–44, 26,809,5550 use women's contraceptive methods covered by the Guidelines).

[86] On average, the Departments expect that approximately half of those students (1,300) are female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. The Departments expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, the Departments assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 2,600. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, the Departments assume they are. Therefore, for the purposes of this estimate, the Departments assume that the effect of these expanded exemptions on student plans of litigating entities includes 2,600 women.

[87] See, *e.g., https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule* ("HHS has now established an accommodation that will allow our ministries to continue offering health

Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.[88] As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.[89] (The Departments take no view on the status of these particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.) Nevertheless, considering all these factors, it generally seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations, the Religious IFC and these final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation."). In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it "is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia." Comments on CMS–9968–ANPRM (dated June 15, 2012).

[88] See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, Advocate Health Care Network, Nos. 16–74, 16–86, 16–258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) ("CHA members have relied for decades that the 'church plan' exemption contained in" ERISA.).

[89] See *https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf;* see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

vi. Combined Estimates of Litigating and Accommodated Entities

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these final rules. In addition to the estimate of 6,400 women of childbearing age that use contraception covered by the Guidelines, who will be affected by use of the expanded exemption among litigating entities, the Departments calculate the following number of women who we estimate to be affected by accommodated entities using the expanded exemption. As noted above, approximately 1,823,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2017. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, the Departments do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, the Departments assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer-sponsored insurance in the private sector, 62.7 percent are covered by self-insured plans and 37.3 percent are covered by fully insured plans.[90] Therefore, corresponding to the approximately 1,823,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 1,084,000 persons were covered by fully insured plans using the accommodation. This yields approximately 2,907,000 persons of all ages and sexes whom the Departments estimate were covered in plans using the accommodation under the previous regulations.

Although recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the previous regulations will continue to opt into it under these final rules and that those entities will cover the substantial majority of persons previously covered in accommodated plans. The data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems and other entities likely to continue using the accommodation constitute over 60 percent of plans using the accommodation, and encompass more than 90 percent of the persons covered in accommodated plans.[91] In other words, plans sponsored by such entities appear to be a majority of plans using the accommodation, and also have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. Moreover, as cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these final rules would not impact the contraceptive coverage their employees receive.

The Departments do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which the Departments lack representative data. Based on these assumptions and without better data available, the Departments assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, the Departments assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons

[90] "Health Insurance Coverage Bulletin" Table 3A, page 14. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[91] The data also reflects a religious university using the accommodation that has publicly affirmed the accommodation is consistent with its religious views, and two houses of worship that are using the accommodation despite already qualifying for the previous exemption. We assume for the purposes of this estimate these three entities will also continue using the accommodation instead of the expanded exemption.

previously covered in accommodated plans.

Applying these percentages to the estimated 2,907,000 persons covered in previously accommodated plans, the Departments estimate that approximately 727,000 persons will be covered in the 109 plans that use the expanded exemption, and 2,180,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, women of childbearing age comprise 20.2 percent of the population, which means that approximately 147,000 women of childbearing age are covered in previously accommodated plans that the Departments estimate will use the expanded exemption. As noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that the Departments expect approximately 64,000 women that use contraception covered by the Guidelines will be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 6,400 women in plans of litigating entities that may be affected by these rules. In order to more broadly estimate the possible effects of these rules, the Departments assume there is no overlap between the two numbers, and therefore that these final rules would affect the contraceptive costs of approximately 70,500 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these final rules is approximately 0.1 percent of the 55.6 million women in private plans that HHS's Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated in 2015 received preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the previous accommodation process, the total amount of contraceptive claims sought for self-insured plans for the 2017 benefit year was $38.5 million.[92] These adjustments covered the cost of contraceptive coverage provided to women. As also discussed above, the Departments estimate that amount corresponded to plans covering 1,823,000 persons. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age, and of those, approximately 43.6 percent use women's contraceptive methods covered by the Guidelines. This amounts to approximately 161,000 women. Therefore, entities using contraceptive user fees adjustments received approximately $239 per year per woman of childbearing age that used contraception covered by the Guidelines and covered in their plans. But in the Religious IFC, we estimated that the average annual cost of contraception per woman per year is $584. As noted above, public commenters cited similar estimates of the annual cost of various contraceptive methods, if calculated for the life of the method's effectiveness. Therefore, to estimate the annual transfer effects of these final rules, the Departments will continue to use the estimate of $584 per woman per year. With an estimated impact of these final rules of 70,500 women per year, the financial transfer effects attributable to these final rules on those women would be approximately $41.2 million.

Some commenters suggested that the Departments' estimate of women affected among litigating entities was too low, but they did not support their proposed higher numbers with citations or specific data that could be verified as more reliable than the estimates in the Religious IFC. Their estimates appeared to be overinclusive, for example, by counting all litigating entities and not just those that may be affected by these rules because they are not in church plans, or by counting all plan participants and not just women of childbearing age that use contraception. Moreover, since the Religious IFC was issued, additional entities have received permanent injunctions against enforcement of any regulations implementing the contraceptive Mandate and so will not be affected by these final rules. Taking all of these factors into account, the Departments are not aware of a better method of estimating the number of women affected by these expanded exemptions.

vii. Alternate Estimates Based on Consideration of Pre-ACA Plans

To account for uncertainty in the estimates above, the Departments conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these final rules.

In 2015, ASPE estimated that 55.6 million women aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.[93] The Religious IFC used this estimate in this second analysis of the possible impact of the expanded exemptions in the interim final rules. ASPE has not issued an update to its report. Some commenters noted that a private organization published a fact sheet in 2017 claiming to make similar estimates based on more recent data, in which it estimated that 62.4 million aged 15 to 64 were covered by private insurance had preventive services coverage under the Affordable Care Act.[94] The primary difference between these numbers appears to be a change in the number of persons covered by grandfathered plans.

The methodology of both reports do not fully correspond to the number the Departments seek to estimate here for the purposes of *Executive Orders 12866 and 13563*. These final rules will not affect all women aged 15 to 64 who are covered by private insurance and have coverage of preventive services under the Affordable Care Act. This is partly because the Departments do not have evidence to suggest that most employers will have sincerely held religious objections to contraceptive coverage and will use the expanded exemptions. In addition, both reports include women covered by plans that are not likely affected by the expanded exemptions for other reasons. For example, even though the estimates in those reports do not include enrollees in public plans such as Medicare or Medicaid, they do include enrollees in plans obtained on the health insurance marketplaces, purchased in the individual market, obtained by self-employed persons, or offered by government employers. Women who purchase plans in the marketplaces, the individual market, or as self-employed persons are not required to use the exemptions in these rules. Government employers are also not affected by the exemptions in these rules.

In response to public comments citing the more recent report, the Departments offer the following estimates based on more recent data than used in the Religious IFC. Data from the U.S. Census Bureau indicates that 167.6 million individuals, male and female, under 65 years of age, were covered by

[92] The amount of user fees adjustments provided was higher than this, since an additional administrative amount was added to the amount of contraceptive costs claimed.

[93] Available at *https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf*.

[94] The commenters cited the National Women's Law Center's Fact Sheet from September 2017, available at *https://nwlc-ciw49tixgw5lbab.stackpathdns.com/wp-content/uploads/2017/09/New-Preventive-Services-Estimates-3.pdf*.

employment-based insurance in 2017.[95] Of those, 50.1 percent were female, that is, 84 million.[96] The most recent Health Insurance Coverage Bulletin from EBSA states that, within employer-sponsored insurance, 76.5% are covered by private sector employers.[97] As noted above, these expanded exemptions do not apply to public sector employers. Assuming the same percentage applies to the Census data for 2017, 64.2 million women under 65 years of age were covered by private sector employment based insurance. EBSA's bulletin also states that, among those covered by private sector employer sponsored insurance, 5% receive health insurance coverage from a different primary source.[98] We assume for the purposes of this estimate that an exemption claimed by an employer under these rules need not affect contraceptive coverage of a person who receives health insurance coverage from a different primary source. Again assuming this percentage applies to the 2017 coverage year, we estimate that 61 million women under 65 years of age received primary health coverage from private sector, employment-based insurance. In conducting this analysis, the Departments also observed that for 3.8 percent of those covered by private sector employment sponsored insurance, the plan was purchased by a self-employed person, not by a third party employer. Self-employed persons who direct firms are not required to use the exemptions in these final rules, but if they do, they would not be losing contraceptive coverage that they want to have, since they would be using the exemption based on their sincerely held religious beliefs. If those persons have employees, the employees would be included in this estimate in the number of people who receive employer sponsored insurance from a third party. Assuming this percentage applies to the 2017 coverage year, we estimate that 58.7 million women under 65 years of age received primary health coverage from private sector insurance from a third party employer plan sponsor.

The Kaiser Family Foundation's Employer Health Benefits Annual Survey 2018 states that 16% of covered workers at all firms are enrolled in a plan grandfathered under the ACA (and thus not subject to the preventive services coverage requirements), but that only 14% of workers receiving coverage from state and local government employer plans are in grandfathered plans.[99] Using the data cited above in EBSA's bulletin concerning the number of persons covered in public and private sector employer sponsored insurance, this suggests 16.6% of persons covered by private sector employer sponsored plans are in grandfathered plans, and 83.4% in non-grandfathered plans.[100] Applying this percentage to the Census data, 49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based, non-grandfathered plans. Census data indicates that among women under age 65, 46.7% are of childbearing age (aged 15 to 44).[101] Therefore, we estimate that 22.9 million women aged 15–44 received primary health insurance coverage from private sector, third party employment based, non-grandfathered insurance plans.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.[102] The 6 percent may have included approximately 1.37 million of the women aged 15 to 44 primarily covered by employer-sponsored insurance plans in the private sector. And as noted above, approximately 43.6 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore, the Departments estimate that 599,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.[103]

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for religious or other reasons. Despite the lack of information about their motives, the Departments attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, the Departments estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in *Hobby Lobby*, where the Court observed that "HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable." 134 S. Ct. at 2774. The Departments are aware of several federal health care conscience

[95] See U.S. Census Bureau Current Population Survey Table HI–01, "Health Insurance Coverage in 2017: All Races," available at *https://www2.census.gov/programs-surveys/cps/tables/hi-01/2018/hi01_1.xls*.

[96] *Id.*

[97] Table 1A, page 5 (stating that in coverage year 2015, 177.5 million persons of all ages were covered by employer sponsored insurance, with 135.7 million of those being covered by private sector employers), available at *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf*.

[98] *Id.* at Table 1C, page 8 (168.7 million persons received health insurance coverage from employer sponsored insurance as their primary source, compared to 177.5 million persons covered by employer sponsored insurance overall).

[99] "Employer Health Benefits: 2018 Annual Survey" at 211, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2018*.

[100] EBSA's bulletin shows 168.7 million persons with primary coverage from employer sponsored insurance, with 131.6 million in the private sector and 37.1 million in the public sector. 16% of 168.7 million is 26.9 million. 14% of 37.1 million is 5.2 million. 26.9 million − 5.2 million is 21.8 million, which is 16.6% of the 131.6 million persons with primary coverage from private sector employer sponsored insurance.

[101] U.S. Census Bureau, Table S0101 "Age and Sex" (available at *https://data.census.gov/cedsci/results/tables?q=S0101:%20AGE%20AND%20SEX&ps=table*&currentPage@1*).

[102] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2010 Annual Survey" at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf*.

[103] Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers' lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these final rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity's mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these final rules.

laws [104] that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but the Departments are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while the Departments consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those reasons used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions, the Departments agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.[105] That means that only approximately 411,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, because these final rules build on previous regulations that already exempted houses of worship and integrated auxiliaries and, as explained above, effectively eliminated obligations to provide contraceptive coverage within objecting self-insured church plans, the Departments attempt to estimate the number of such employers whose employees would not be affected by these rules. In attempting to estimate the number of such employers, the Departments consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the United States,[106] 197 Catholic dioceses,[107] 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.[108] Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so the Departments use the number of schools as an estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention covering 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.[109] Christian Brothers is a plan that covers Catholic organizations including Catholic churches and integrated auxiliaries, which are estimated above, but has also said in litigation that it covers about 500 additional entities that are not exempt as churches.[110] In total, therefore, without having certain data on the number of entities exempt under the previous rules, the Departments estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous regulations. The Departments do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include "churches, mission-sending agencies, hospitals, educational institutions and other related ministries." Using that ratio, the Departments estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 women would be of childbearing age, and 32,100 may use contraceptives covered by the Guidelines.

Taking all of these factors into account, the Departments estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous regulations nor were participants in self-insured church plans that oppose contraceptive coverage, covered approximately 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines. But to estimate the likely actual transfer impact of these final rules, the Departments must estimate not just the number of such women covered by those entities, but how many of those entities would actually qualify for, and use, the expanded exemptions.

The Departments do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous regulations on this matter, the Departments are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, the Departments believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 126,400 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. Consequently, as explained below, the Departments believe that the potential impact of these final rules falls substantially below the $100 million threshold for an economically significant major rule.

First, as mentioned, the Departments are not aware of information, or of data from public comments, that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or, specifically, religious beliefs, as opposed to having done so for other reasons. It would seem reasonable to assume that many of those entities did not do so based on sincerely held religious beliefs. According to a 2016 poll, only 4% of Americans believe that using contraceptives is morally wrong (including from a religious perspective).[111] In addition,

[104] For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

[105] John Asker, et al., "Corporate Investment and Stock Market Listing: A Puzzle?" 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at *https://doi.org/10.1093/rfs/hhu077*. This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, "The number of publicly-traded US companies is down 46% in the past two decades," *Yahoo! Finance* (Aug. 8, 2016), available at *https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html*.

[106] Roman Catholic Diocese of Reno, "Diocese of Reno Directory: 2016–2017," available at *http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf*.

[107] Wikipedia, "List of Catholic dioceses in the United States," available at *https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States*.

[108] National Catholic Educational Association, "Catholic School Data," available at *http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx*.

[109] Guidestone Financial Resources, "Who We Serve," available at *https://www.guidestone.org/AboutUs/WhoWeServe*.

[110] The Departments take no view on the status of particular plans under the Employee Retirement Income Security Act of 1974 (ERISA), but simply make this observation for the purpose of seeking to estimate the impact of these final rules.

[111] Pew Research Center, "Where the Public Stands on Religious Liberty vs. Nondiscrimination"

various reasons exist for some employers not to return to a pre-ACA situation in which they did not provide contraceptive coverage, such as avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.[112] Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees and, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

It may not be the case that all entities that objected on religious grounds to contraceptive coverage before the ACA brought suit against the Mandate. However, it is worth noting that, while less than 100 for-profit entities challenged the Mandate in court (and an unknown number joined two newly formed associational organizations bringing suit on their behalf), there are more than 3 million for-profit private sector establishments in the United States that offer health insurance.[113] Six percent of those would be 185,000, and one third of that number would be 62,000. The Departments consider it unlikely that tens or hundreds of thousands of for-profit private sector establishments omitted contraceptive coverage pre-ACA specifically because of sincerely held religious beliefs, when, after six years of litigation and multiple public comment periods, the Departments are aware of less than 100 such entities. The Departments do not know how many additional nonprofit entities would use the expanded exemptions, but as noted above, under the rules predating the Religious IFC, tens of thousands were already exempt as churches or integrated auxiliaries, or were covered by self-insured church plans that are not penalized if no contraceptive coverage is offered.

Finally, among entities that omitted contraceptive coverage based on sincerely held conscientious objections as opposed to other reasons, it is likely that some, albeit a minority, did so based on moral objections that are non-religious, and therefore would not be compassed by the expanded exemptions in these final rules.[114] Among the general public, polls vary about religious beliefs, but one prominent poll shows that 13 percent of Americans say they do not believe in God or have no opinion on the question.[115] Therefore, the Departments estimate that, of the entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, a small fraction did so based on sincerely held non-religious moral convictions, and therefore would not be affected by the expanded exemption provided by these final rules for religious beliefs.

For the reasons stated above, the Departments believe it would be incorrect to assume that all or even most of the plans that did not cover contraceptives before the ACA did so on the basis of religious objections. Instead, without data available on the reasons those plans omitted contraceptive coverage before the ACA, we assume that no more than one third of those plans omitted contraceptive coverage based on sincerely held religious beliefs. Thus, of the estimated 379,000 women aged 15 to 44 that use contraceptives covered by the Guidelines, who received primary coverage from plans of private, non-publicly traded, third party employers that did not cover contraception pre-Affordable Care Act, and whose plans were neither exempt nor omitted from mandatory contraceptive coverage under the previous regulations, we estimate that no more than 126,400 women would be in plans that will use these expanded exemptions.

viii. Final Estimates of Persons Affected by Expanded Exemptions

Based on the estimate of an average annual expenditure on contraceptive products and services of $584 per user, the effect of the expanded exemptions on 126,400 women would give rise to approximately $73.8 million in potential transfer impact. It is possible, however, that premiums would adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As referenced elsewhere in this analysis, such women may make up approximately 8.8 percent of the covered population,[116] in which case the offset would also be approximately 8.8 percent, yielding a potential transfer of $67.3 million.

Thus, in their most expansive estimate, the Departments conclude that no more than approximately 126,400 women would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these final rules. The Departments estimate this financial transfer to be approximately $67.3 million. This falls substantially below the $100 million threshold for an economically significant and major rule.

As noted above, the Departments view this alternative estimate as being the highest possible bound of the transfer effects of these rules, but believe the number of establishments that will actually exempt their plans as the result of these rules will be far fewer than contemplated by this estimate. The Departments make these estimates only for the purposes of determining whether the rules are economically significant under Executive Orders 12866 and 13563.

After reviewing public comments, both those supporting and those disagreeing with these estimates and similar estimates from the Religious IFC, and because the Departments do not have sufficient data to precisely

at page 26 (Sept. 28, 2016), available at *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf.*

[112] On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered "yes" or "don't know" to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule's effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

[113] Tables I.A.1 and I.A.2, Medical Expenditure Panel Survey, "Private-Sector Data by Firm Size, Industry Group, Ownership, Age of Firm, and Other Characteristics: 2017." HHS Agency for Healthcare Research and Quality (indicating total number of for-profit incorporated, for-profit unincorporated, and non-profit establishments in the United States, and the percentage of each that offer health insurance), available at *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia1.htm* and *https://meps.ahrq.gov/data_stats/summ_tables/insr/national/series_1/2017/tia2.htm*, 2523.

[114] Such objections may be encompassed by companion final rules published elsewhere in today's **Federal Register**. Those final rules, however, are narrower in scope than these final rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

[115] Gallup, "Religion," available at *https://news.gallup.com/poll/1690/religion.aspx.*

[116] As cited above, women of childbearing age are 20.2 percent of woman aged 15–65, and 43.6 percent of women of childbearing age use contraceptives covered by the Guidelines.

estimate the amount by which these factors render our estimate too high, or too low, the Departments simply conclude that the financial transfer falls substantially below the $100 million threshold for an economically significant rule based on the calculations set forth above.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. The Religious IFC was an interim final rule with comment period, and in these final rules, the Departments adopt the Religious IFC as final with certain changes. These final rules are, thus, being issued after a notice and comment period.

The Departments also carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866 and do not expect that these final rules will have a significant economic effect on a substantial number of small entities. These final rules will not result in any additional costs to affected entities, and, in many cases, may relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization—businesses and organizations that would otherwise be faced with the dilemma of complying with the Mandate (and violating their religious beliefs) or following their beliefs (and incurring potentially significant financial penalties for noncompliance)—the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.

Recommendations to minimize the information collection burden on the affected public, including automated collection techniques. In the October 13, 2017 (82 FR 47792) interim final rules, we solicited public comment on each of these issues for the following sections of the rule containing information collection requirements (ICRs). A description of the information collection provisions implicated in these final rules is given in the following section with an estimate of the annual burden. The burden related to these ICRs received emergency review and approval under OMB control number 0938–1344. They have been resubmitted to OMB in conjunction with these final rules and are pending re-approval. The Departments sought public comments on PRA estimates set forth in the Religious IFC, and are not aware of significant comments submitted that suggest there is a better way to estimate these burdens.

1. Wage Data

Average labor costs (including 100 percent fringe benefits and overhead) used to estimate the costs are calculated using data available derived from the Bureau of Labor Statistics.[117]

TABLE 1—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

BLS occupation title	Occupational code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Executive Secretaries and Executive Administrative Assistants	43–6011	$27.84	$27.84	$55.68
Compensation and Benefits Manager	11–3111	61.01	61.01	122.02
Legal Counsel	23–1011	67.25	67.25	134.50
Senior Executive	11–1011	93.44	93.44	186.88
General and Operations Managers	11–1021	58.70	58.70	117.40

2. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under these final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations (80 FR 41318).

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party

[117] May 2016 National Occupational Employment and Wage Estimates United States found at *https://www.bls.gov/oes/current/oes_nat.htm*.

administrator). As explained above, HHS assumes that, among the 209 entities the Departments estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.[118] HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of $55.68 per hour, 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour, 5 minutes for legal counsel at a cost of $134.50 per hour, and 5 minutes by a senior executive at a cost of $186.88 per hour) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost of approximately $74.96 for a total hour burden of approximately 7.5 hours and an associated equivalent cost of approximately $675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so that each will account for approximately 3.75 burden hours with an equivalent cost of approximately $337.

HHS estimates that each self-certification or notice to HHS will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be $0.55. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately $2.75 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so that each will account for $1.38 of the cost burden.

[118] For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

3. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations (80 FR 41318), a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language previously provided by HHS or substantially similar language.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at $55.68 per hour) and 15 minutes of management review (at $117.40 per hour) to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an associated cost of approximately $85.03. The total burden for all 109 issuers or third party administrators will be 136 hours, with an associated cost of approximately $9,268. As DOL and HHS share jurisdiction, they are splitting the burden each will account for 68 burden hours with an associated cost of $4,634, with approximately 55 respondents.

The Departments estimate that approximately 2,180,000 plan participants and beneficiaries will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. We reach this estimate using calculations set forth above, in which we used 2017 data available to HHS for contraceptive user fees adjustments to estimate that approximately 2,907,000 plan participants and beneficiaries were covered by plans using the accommodation. We further estimated that the 100 entities that previously used the accommodation and will continue doing so will cover approximately 75 percent of the persons in all accommodated plans, based on HHS data concerning accommodated self-insured plans that indicates plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As noted above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans. The Departments do not have specific data on which plans of which employer sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. The Departments assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data.

Based on these assumptions and without better data available, the Departments estimate that previously accommodated entities encompassed approximately 2,907,000 persons; the estimated 100 entities that previously used the accommodation and continue to use it will account for 75 percent of those persons (that is, approximately 2,180,000 persons); and the estimated 109 entities that previously used the accommodation and will now use their exempt status will account for 25 percent of those persons (that is, approximately 727,000 persons). It is not known how many persons will be covered in the plans of the 9 entities we estimate will newly use the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity as the 100 entities encompassing 2,180,000

persons, the Departments estimate that all 109 accommodated entities will encompass approximately 2,376,000 covered persons.

The Departments assume that sending one notice to each policyholder will satisfy the need to send the notices to all participants and dependents. Among persons covered by insurance plans sponsored by large employers in the private sector, approximately 50.1 percent are participants and 49.9 percent are dependents.[119] For 109 entities, the total number of notices will be 1,190,613. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.[120] Therefore, approximately 551,254 notices will be mailed. HHS estimates that each notice will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.55. The total cost for sending approximately 551,254 notices by mail will be approximately $303,190. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $151,595 of the cost burden.

4. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization that now wishes to take advantage of the expanded exemption may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to send the notification; the issuer or third party administrator can send the notice on behalf of the entity. For the purpose of calculating the ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke their use of the accommodation fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of $117.40 per hour, 30 minutes for legal counsel at a cost of $134.50 per hour, 1 hour for clerical staff at a cost of $55.68 per hour). The burden per respondent will be 2 hours with an associated cost of approximately $182; for 109 entities, the total hour burden will be 218 hours with an associated cost of approximately $19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an associated cost of approximately $9,899.

As discussed above, HHS estimates that there are approximately 727,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[121] As before, the Departments use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 364,102 notices will be distributed, of which 168,579 notices will be mailed. HHS estimates that each mailed notice will require $0.50 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.55. The total cost for sending approximately 168,579 notices by mail is approximately $93,545. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 182,051 notices, with an associated cost of approximately $46,772.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB Control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
Self-Certification or Notices to HHS	0938–1344	*5	5	0.83	3.75	$89.95	$337	$339
Notice of Availability of Separate Payments for Contraceptive Services	0938–1344	*55	595,307	1.25	68.13	68.02	4,634	156,229
Notice of Revocation of Accommodation	0938–1344	*55	182,051	2.00	109	90.82	9,899	56,671
Total		*115	777,363		180.88		14,870	213,239

* The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

[119] "Health Insurance Coverage Bulletin" Table 4, page 21. Using Data for the March 2016 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2016.pdf.*

[120] According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61 percent of internet users use online banking, which is used as the proxy for the number of internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

[121] In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, the Departments indicated that we do not know the extent to which the number of women in accommodated plans affected by these final rules overlap with the number of women in plans offered by litigating entities that will be affected by these final rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

5. Submission of PRA-Related Comments

We have submitted a copy of this rule to OMB for its review of the rule's information collection and recordkeeping requirements. These requirements are not effective until they have been approved by OMB.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov*. PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

The Religious final rules amended the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer revokes their accommodation; these final rules confirm as final the Religious IFC provisions on the accommodation process. DOL submitted the ICRs to OMB in order to obtain OMB approval under the PRA for the regulatory revision. In an effort to consolidate the number of information collection requests, DOL is combining the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150 and discontinuing OMB control number 1210–0152. Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur $0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 1,190,613 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke their use of the accommodation (in favor of the expanded exemption) and will therefore be required to cause the Notice of Revocation of Accommodation to be sent, with the issuer or third party administrator able to send the notice on behalf of the entity. These entities will spend approximately two hours in preparation time and incur $0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 364,102 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.

Agency: DOL–EBSA.

Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.

OMB Numbers: 1210–0150.

Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.

Total Respondents: 114 [122] (combined with HHS total is 227).

Total Responses: 777,362 (combined with HHS total is 1,554,724).

Frequency of Response: On occasion.

Estimated Total Annual Burden Hours: 181 (combined with HHS total is 362 hours).

Estimated Total Annual Burden Cost: $197,955 (combined with HHS total is $395,911).

Type of Review: Revised Collection.

Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, "[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." In addition, agencies are directed to "take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the states more flexibility and control to create a freer and open healthcare market." These final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these final rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.[123] However, in order to avoid double-counting with the Religious IFC, which has already been tallied as an Executive Order 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

[122] Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

[123] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (Dominic J. Mancini, "Guidance Implementing Executive Order 13771, Titled "Reducing Regulation and Controlling Regulatory Costs," Office of Mgmt. & Budget (Apr. 5, 2017). *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year." In 2018, that threshold after adjustment for inflation is $150 million. For purposes of the Unfunded Mandates Reform Act, the Religious IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of $150 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These final rules do not have any federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

V. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code, and Public Law 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4).

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Pub. L. 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4); Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701); and Public Law 103–141, 107 Stat. 1488 (42 U.S.C. 2000bb–2000bb–4).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

■ 2. Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 3. Section 54.9815–2713A is revised to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the

Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(b) *Optional accommodation—self-insured group health plans*—(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services) will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not

apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): "Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer]."

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be

incorrect, the issuer is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(f) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(g) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

§ 54.9815–2713T [Removed]

■ 4. Section 54.9815–2713T is removed.

§ 54.9815–2713AT [Removed]

■ 5. Section 54.9815–2713AT is removed.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor adopts as final the interim final rules amending 29 CFR part 2590 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read, as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713A is amended by:
■ a. Revising paragraph (a)(5);
■ b. Redesignating paragraphs (e) and (f) as paragraphs (f) and (g); and
■ c. Adding new paragraph (e).

The revision and addition read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) * * *

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on the date on which these final rules go into effect, by an issuer or third party administrator through the accommodation process, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after the date on which these final rules go into effect, if contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 2590.715–2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47792) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 8. The authority citation for part 147 is revised to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 9. Section 147.131 is amended by:
■ a. Revising paragraph (c)(4);
■ b. Redesignating paragraphs (f) and (g) as (g) and (h); and
■ c. Adding new paragraph (f).

The revision and addition read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

* * * * *

(c) * * *

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation, as specified herein.

(i) *Transitional rule*—If contraceptive coverage is being offered on January 14, 2019, by an issuer through the accommodation process, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, such eligible organization may revoke its use of the accommodation process effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation.

(ii) *General rule*—In plan years that begin after January 14, 2019, if

contraceptive coverage is being offered by an issuer through the accommodation process, an eligible organization's revocation of use of the accommodation process will be effective no sooner than the first day of the first plan year that begins on or after 30 days after the date of the revocation.

* * * * *

(f) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (d) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any applicable requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (d) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

* * * * *

■ 10. Section 147.132 is amended by:
■ a. Revising paragraph (a)(1) introductory text;
■ b. Redesignating paragraphs (a)(1)(ii) and (iii) as paragraphs (iii) and (iv);
■ c. Adding new paragraph (a)(1)(ii);
■ d. Revising newly designated paragraph (a)(1)(iii);
■ e. Revising newly designated paragraph (a)(1)(iv); and
■ f. Revising paragraphs (a)(2) and (b).

The revisions and addition read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) A group health plan, and health insurance coverage provided in connection with a group health plan, where the plan or coverage is established or maintained by a church, an integrated auxiliary of a church, a convention or association of churches, a religious order, a nonprofit organization, or other non-governmental organization or association, to the extent the plan sponsor responsible for establishing and/or maintaining the plan objects as specified in paragraph (a)(2) of this section. The exemption in this paragraph applies to each employer, organization, or plan sponsor that adopts the plan;

(iii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iv) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this subparagraph (iv), the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held religious beliefs, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018–24512 Filed 11–7–18; 4:15 pm]
BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9841]

RIN 1545–BN91

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9925–F]

RIN 0938–AT46

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: These rules finalize, with changes based on public comments, the interim final rules issued in the **Federal Register** on October 13, 2017 concerning moral exemptions and accommodations regarding coverage of certain preventive services. These rules finalize expanded exemptions to protect moral beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the U.S. Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave in place an optional "accommodation" process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These regulations are effective on January 14, 2019.

FOR FURTHER INFORMATION CONTACT:

Jeff Wu at (301) 492–4305 or *marketreform@cms.hhs.gov* for the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

Amber Rivers or Matthew Litton at (202) 693–8335 for Employee Benefits Security Administration (EBSA), Department of Labor (DOL).

William Fischer at (202) 317–5500 for Internal Revenue Service, Department of the Treasury.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit DOL's website (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's website (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov*.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose

The primary purpose of these final rules is to finalize, with changes in response to public comments, the interim final regulations with requests for comments (IFCs) published in the **Federal Register** on October 13, 2017 (82 FR 47838), "Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act" (the Moral IFC). The rules are necessary to protect sincerely held moral objections of certain entities and individuals. The rules, thus, minimize the burdens imposed on their moral beliefs, with regard to the discretionary requirement that health plans cover certain contraceptive services with no cost-sharing, which was created by HHS through guidance promulgated by the Health Resources and Services

Administration (HRSA), pursuant to authority granted by the ACA in section 2713(a)(4) of the Public Health Service Act. In addition, the rules finalize references to these moral exemptions in the previously created accommodation process that permit entities with certain objections voluntarily to continue to object while the persons covered in their plans receive contraceptive coverage or payments arranged by their issuers or third party administrators. The rules do not remove the contraceptive coverage requirement generally from HRSA's guidelines. The changes to the rules being finalized will ensure clarity in implementation of the moral exemptions so that proper respect is afforded to sincerely held moral convictions in rules governing this area of health insurance and coverage, with minimal impact on HRSA's decision to otherwise require contraceptive coverage.

2. Summary of the Major Provisions

a. Moral Exemptions

These rules finalize exemptions provided in the Moral IFC for the group health plans and health insurance coverage of various entities and individuals with sincerely held moral convictions opposed to coverage of some or all contraceptive or sterilization methods encompassed by HRSA's guidelines. As in the Moral IFC, the exemptions include plan sponsors that are nonprofit organization plan sponsors or for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The exemptions also continue to include institutions of higher education in their arrangement of student health insurance coverage; health insurance issuers (but only with respect to plans that are otherwise also exempt under the rules); and objecting individuals with respect to their own coverage, where their health insurance issuer and plan sponsor, as applicable, are willing to provide coverage complying with the individual's moral objection. After considering public comments, the Departments have decided not to extend the moral exemptions to non-federal governmental entities at this time, although individuals receiving employer-sponsored insurance from a governmental entity may use the individual exemption if the other terms of the individual exemption apply, including that their employer is willing to offer them a plan consistent with their moral objection.

In response to public comments, various changes are made to clarify the intended scope of the language in the Moral IFC's exemptions. The prefatory exemption language is clarified to ensure exemptions apply to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections. The Departments add language to specify that the exemption for institutions of higher education applies to non-governmental entities. The Departments also modified language describing the moral objection applicable to the exemptions, to specify that the entity objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable) either: Coverage or payments for some or all contraceptive services; or a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

The Departments also clarify language in the exemption applicable to plans of objecting individuals. The clarification is made to ensure that the HRSA guidelines do not prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. The exemption adds that, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

b. References to Moral Exemptions in Accommodation Regulations and in Regulatory Restatement of Statutory Language

These rules finalize without change the references to the moral exemptions that were inserted by the Moral IFC into the rules that regulatorily restate the statutory language from section 2713(a) and (a)(4) of the Public Health Service Act. Similarly, these rules finalize without change from the Moral IFC references to the moral exemptions that were inserted into the regulations governing the optional accommodation process. These references operationalize the effect of the moral exemptions rule, and they allow contraceptive services to be made available to women if any employers with non-religious moral objections to contraceptive coverage choose to use the optional accommodation process.

3. Summary of Costs, Savings and Benefits of the Major Provisions

Provision	Savings and Benefits	Costs
Finalizing insertion of references to moral exemptions into restatement of statutory language from section 2713(a) and (a)(4) of the Public Health Service Act.	These provisions, finalized without change, are for the purpose of inserting references to the moral exemptions into the regulatory restatement of section 2713(a) and (a)(4) of the Public Health Service Act, which already references the religious exemptions. This operationalizes the moral exemptions in each of the tri-agencies' rules. We estimate no economic savings or benefit from finalizing this part of the rule, but consider it a deregulatory action to minimize the regulatory impact beyond the scope set forth in the statute.	We estimate no costs from finalizing this part of the rule.

Provision	Savings and Benefits	Costs
Finalized moral exemptions	The moral exemptions to the contraceptive coverage requirement are finalized with technical changes. Their purpose is to relieve burdens that some entities and individuals experience from being forced to choose between, on the one hand, complying with their moral beliefs and facing penalties from failing to comply with the contraceptive coverage requirement, and on the other hand, providing (or, for individuals, obtaining) contraceptive coverage in violation of their sincerely held moral beliefs.	We estimate there will be only a small amount of costs for these exemptions, because they will primarily be used by organizations and individuals that do not want contraceptive coverage. To the extent some other employers will use the exemption where there will be transfer costs for women previously receiving contraceptive coverage who will no longer receive that coverage, we expect those costs to be minimal due to the small number of entities expected to use the exemptions with non-religious moral objections. We estimate the transfer costs will amount to $8,760.
Finalizing insertion of references to moral exemptions into optional accommodation regulations.	These provisions, finalized without change, will allow organizations with moral objections to contraceptive coverage on the basis of sincerely held moral convictions to use the accommodation as an optional process. These provisions will allow contraceptive coverage to be made available to women covered by plans of employers that object to contraceptive coverage but do not object to their issuers or third party administrators arranging for such coverage to be provided to persons covered by their plans.	We do not estimate any entities with non-religious moral objections to use the accommodation process at this time.

B. Background

Over many decades, Congress has protected conscientious objections including based on moral convictions in the context of health care and human services, and including health coverage, even as it has sought to promote access to health services.[1] In 2010, Congress enacted the Patient Protection and Affordable Care Act (PPACA) (Pub. L. 111–148) (March 23, 2010). Congress enacted the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152) on March 30, 2010, which, among other things, amended PPACA. As amended by HCERA, PPACA is known as the Affordable Care Act (ACA).

The ACA reorganized, amended, and added to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code), in order to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

In section 2713(a)(4) of the PHS Act (hereinafter "section 2713(a)(4)"), Congress provided administrative discretion to require that certain group health plans and health insurance issuers cover certain women's preventive services, in addition to other preventive services required to be covered in section 2713. Congress granted that discretion to the Health Resources and Services Administration (HRSA), a component of the U.S. Department of Health and Human Services (HHS). Specifically, section 2713(a)(4) allows HRSA discretion to specify coverage requirements, "with respect to women, such additional preventive care and screenings as provided for in comprehensive guidelines supported" by HRSA (the "Guidelines").

Since 2011, HRSA has exercised that discretion to require coverage for, among other things, certain contraceptive services.[2] In the same

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their "religious beliefs or moral convictions"); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act), Public Law 115–141, 132 Stat. 348, 764 (Mar. 23, 2018) (protecting any "health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion for any reason); *Id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions"); *Id.* at Div. E, Sec. 808 (regarding any requirement of "the provision of contraceptive coverage by health insurance plans" in the District of Columbia, "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions."); *Id.* at Div. K, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their "religious or conscientious commitment to offer only natural family planning"); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on "religious beliefs or moral objections"); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare+Choice, now Medicare Advantage, managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on "conscience" as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on "religious beliefs or moral convictions"); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); *see also* 8 U.S.C. 1182(g) (protecting vaccination objections by "aliens" due to "religious beliefs or moral convictions"); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on "moral or religious convictions"); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their "religious or moral objection").

[2] The references in this document to "contraception," "contraceptive," "contraceptive coverage," or "contraceptive services" generally include all contraceptives, sterilization, and related patient education and counseling, required by the Women's Preventive Guidelines, unless otherwise indicated. The Guidelines issued in 2011 referred to "Contraceptive Methods and Counseling" as "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." *https://www.hrsa.gov/womens-guidelines/index.html.* The Guidelines as amended in December 2016 refer, under the header "Contraception," to: "the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family

time period, the administering agencies—HHS, the Department of Labor, and the Department of the Treasury (collectively, "the Departments" [3])—exercised discretion to allow exemptions to those requirements by issuing rulemaking various times, including issuing and finalizing three interim final regulations prior to 2017.[4] In those regulations, the Departments crafted exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services, changed the scope of those exemptions and accommodations, and solicited public comments on a number of occasions. Public comments were submitted on various iterations of the regulations issued before 2017, and some of those comments supported expanding the exemptions to include those who oppose the contraceptive coverage mandate for either religious "or moral" reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.[5]

During the period when the Departments were publishing and modifying the regulations, organizations and individuals filed dozens of lawsuits challenging the contraceptive coverage requirement and regulations (hereinafter, the "contraceptive Mandate," or the "Mandate"). Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. For-profit entities with religious objections won various court decisions leading to the Supreme Court's ruling in *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[6] Later, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On May 16, 2016, the Supreme Court issued a per curiam decision, vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments' favor—and remanding the cases "in light of the substantial clarification and refinement in the positions of the parties" that had been filed in supplemental briefs. *Zubik* v. *Burwell,* 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would "allow the parties sufficient time to resolve any outstanding issues between them." *Id.*

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations stated that they believe some methods classified by the Food and Drug Administration (FDA) as contraceptives may have an abortifacient effect and, therefore, in their view, are morally equivalent to abortion to which they have a moral objection. Under regulations preceding October 2017, these organizations neither received an exemption from the Mandate nor qualified for the accommodation. For example, March for Life filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, 77 FR 8727, March for Life argued that the Departments' stated interests behind the Mandate were only advanced among women who "want" the coverage so as to prevent "unintended" pregnancy. March for Life contended that, because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments' interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and, therefore, was arbitrary and capricious in violation of the APA. March for Life further contended that, because the Departments concluded the government's interests were not undermined by exempting houses of worship and integrated auxiliaries (based on the assumption that such entities are relatively more likely than other nonprofits with religious objections to have employees that share their views against certain contraceptives), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and, therefore, violated their right of equal protection under the Due Process Clause.

March for Life's employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violated their rights under RFRA by making it impossible for them to obtain health coverage consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate's requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. *Real*

planning practices, and sterilization procedures," "contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.*, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method)," and "instruction in fertility awareness-based methods, including the lactation amenorrhea method." *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[3] Note, however, that in sections under headings listing only two of the three Departments, the term "Departments" generally refers only to the two Departments listed in the heading.

[4] Interim final regulations on July 19, 2010, at 75 FR 41726 (July 2010 interim final regulations); interim final regulations amending the July 2010 interim final regulations on August 3, 2011, at 76 FR 46621; final regulations on February 15, 2012, at 77 FR 8725 (2012 final regulations); an advance notice of proposed rulemaking (ANPRM) on March 21, 2012, at 77 FR 16501; proposed regulations on February 6, 2013, at 78 FR 8456; final regulations on July 2, 2013, at 78 FR 39870 (July 2013 final regulations); interim final regulations on August 27, 2014, at 79 FR 51092 (August 2014 interim final regulations); proposed regulations on August 27, 2014, at 79 FR 51118 (August 2014 proposed regulations); final regulations on July 14, 2015, at 80 FR 41318 (July 2015 final regulations); and a request for information on July 26, 2016, at 81 FR 47741 (RFI), which was addressed in an FAQ document issued on January 9, 2017, available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

[5] *See, for example,* Denise M. Burke, Re: file code CMS–9968–P, *Regulations.gov* (posted May 5, 2013), *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115;* Comment, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-54142;* David Sater, Re: CMS–9931–NC: Request for Information, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-54218;* Comment, *Regulations.gov* (posted Oct. 26, 2016), *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

[6] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. *See* 134 S. Ct. at 2774.

Alternatives, Inc. v. *Burwell*, 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims, while not specifically ruling on the APA claim, and issued a permanent injunction against the Departments that is still in place. *March for Life* v. *Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in *March for Life* is pending and has been stayed since early 2016. In another case, federal district and appellate courts in Pennsylvania disagreed with the reasoning in *March for Life*, and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. *Real Alternatives*, 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in *Real Alternatives* v. *Sec'y of HHS* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. 867 F.3d 338, 367 (3d Cir. 2017) (Jordan, J., dissenting).

The Departments most recently solicited public comments on these issues again in two interim final regulations with request for comments published in the **Federal Register** on October 13, 2017: The regulations (82 FR 47838) (the Moral IFC) that are being finalized with changes here, and the regulations (82 FR 47792) (the Religious IFC) published on the same day as the Moral IFC, which are being finalized with changes in the companion final rules published elsewhere in today's **Federal Register**.

In the preamble to the Moral IFC, the Departments explained several reasons why, after exercising our discretion to reevaluate the exemptions and accommodations for the contraceptive Mandate, we sought public comment on whether to protect moral convictions in the Moral IFC and these final rules. The Departments noted that we considered, among other things, Congress's history of providing protections for moral convictions regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the text, context, and intent of section 2713(a)(4) and the ACA; Executive Order 13798, "Promoting Free Speech and Religious Liberty" (May 4, 2017); previously submitted public comments; and the extensive litigation over the contraceptive Mandate. The Departments concluded that it was appropriate that HRSA take into account the moral convictions of certain employers, individuals and health insurance issuers where the coverage of contraceptive services is concerned. Comments were requested on the interim final regulations.

After consideration of the comments and feedback received from stakeholders, the Departments are finalizing the Moral IFC, with changes based on comments as indicated herein.[7]

II. Overview of the Final Rules and Public Comments

During the 60-day comment period for the Moral IFC, which closed on December 5, 2017, the Departments received over 54,000 public comment submissions, which are posted to *www.regulations.gov*.[8] Below, the Departments provide an overview of the final rules and address the issues raised in the comments we received.

A. Moral Exemptions and Accommodation in General

These rules expand exemptions to protect certain entities and individuals with moral convictions that oppose contraception whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the ACA. These rules do not alter the discretion of HRSA, a component of HHS, to maintain the Guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also make available to exempt organizations the accommodation process, which was previously established in response to some objections of religious organizations, as an optional process for exempt entities that wish to use it voluntarily. These rules do not alter multiple other federal programs that provide free or subsidized contraceptives or related education and counseling for women at risk of unintended pregnancy.[9]

1. The Departments' Authority To Mandate Coverage or Provide Exemptions

The Departments received conflicting comments on their legal authority to provide exemptions and accommodations to the Mandate. Some commenters agreed that the Departments are legally authorized to provide expanded exemptions and an accommodation for moral convictions, noting that there was no requirement of contraceptive coverage in the ACA and no prohibition on providing moral exemptions in Guidelines issued under section 2713(a)(4). Other commenters, however, asserted that the Departments have no legal authority to provide any exemptions to the contraceptive Mandate, contending, based on statements in the ACA's legislative history, that the ACA requires contraceptive coverage. Still other commenters contended that the Departments are legally authorized to provide the religious exemptions that existed prior to the 2017 IFCs, but not to protect moral convictions.

The Departments conclude that we are legally authorized to provide the exemption and accommodation for moral convictions set forth in the Moral IFC and these final rules. These rules concern section 2713 of the PHS Act, as incorporated into ERISA and the Code. Congress has granted the Departments legal authority, collectively, to administer these statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Where it applies, section 2713(a)(4) requires coverage without cost sharing for "such additional" women's preventive care and screenings "as provided for" and "supported by" guidelines developed by HHS acting through HRSA. When Congress enacted this provision, those Guidelines did not exist. And nothing in the statute mandated that the Guidelines had to include contraception, let alone for all types of employers with covered plans. Instead, section 2713(a)(4) provided a

[7] The Department of the Treasury and Internal Revenue Service published proposed and temporary regulations as part of the joint rulemaking of the Moral IFC. The Departments of Labor and HHS published their respective rules as interim final rules with request for comments and are finalizing their interim final rules in these final rules. The Department of the Treasury and Internal Revenue Service are finalizing their regulations.

[8] *See Regulations.gov* at *https://www.regulations.gov/searchResults?rpp=25&so=DESC&sb=postedDate&po=0&cmd=12%7C05%7C17-12%7C05%7C17&dktid=CMS-2017-0133* and *https://www.regulations.gov/docketBrowser?rpp=25&so=ASC&sb=postedDate&po=100&D=IRS-2017-0015*. Some of those submissions included form letters or attachments that, while not separately tabulated at regulations.gov, together included comments from, or were signed by, possibly over a hundred thousand separate persons. The Departments reviewed all of the public comments and attachments.

[9] *See, for example*, Family Planning grants in 42 U.S.C. 300, *et seq.*; the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.*; the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.*; Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

positive grant of authority for HSRA to develop those Guidelines, thus delegating authority to HHS to shape that development, as the administering agency of HRSA, and to all three agencies as the administering agencies of the statutes by which the Guidelines are enforced. *See* 26 U.S.C. 9833; 29 U.S.C. 1191(c), 42 U.S.C. 300gg–92. That is especially true for HHS, as HRSA is a component of HHS that was unilaterally created by the agency and thus is subject to the agency's general supervision, *see* 47 FR 38409 (August 31, 1982). Thus, nothing prevented HRSA from creating an exemption from otherwise-applicable guidelines or prevented HHS and the other agencies from directing that HRSA create such an exemption.

Congress did not specify the extent to which HRSA must "provide for" and "support" the application of Guidelines that it chooses to adopt. HRSA's authority to support "comprehensive guidelines" involves determining both the types of coverage and scope of that coverage. Section 2714(a)(4) requires coverage for preventive services only "as provided for in comprehensive guidelines supported by [HRSA]." That is, services are required to be included in coverage only to the extent that the Guidelines supported by HRSA provide for them. Through use of the word "as" in the phrase "as provided for," it requires that HRSA support how those services apply—that is, the manner in which the support will happen, such as in the phrase "as you like it." [10] When Congress means to require certain activities to occur in a certain manner, instead of simply authorizing the agency to decide the manner in which they will occur, Congress knows how to do so. *See for example,* 42 U.S.C. 1395x ("The Secretary shall establish procedures to make beneficiaries and providers aware of the requirement that a beneficiary complete a health risk assessment *prior to or at the same time as* receiving personalized prevention plan services.") (emphasis added). Thus, the inclusion of "as" in section 300gg–13(a)(3), and its absence in similar neighboring provisions, shows that HRSA has discretion whether to support how the preventive coverage mandate applies—it does not refer to the timing of the promulgation of the Guidelines.

Nor is it simply a textual aberration that the word "as" is missing from the other three provisions in section 2713(a) of the PHS Act. Rather, this difference mirrors other distinctions within that section that demonstrate that Congress intended HRSA to have the discretion the Agencies invoke. For example, sections (a)(1) and (a)(3) require "evidence-based" or "evidence-informed" coverage, while section (a)(4) does not. This difference suggests that the Agencies have the leeway to incorporate policy-based concerns into their decision-making. This reading of section 2713(a)(4) also prevents the statute from being interpreted in a cramped way that allows no flexibility or tailoring, and that would force the Departments to choose between ignoring religious objections in violation of RFRA or else eliminating the contraceptive coverage requirement from the Guidelines altogether. The Departments instead interpret section 2713(a)(4) as authorizing HRSA's Guidelines to set forth both the kinds of items and services that will be covered, and the scope of entities to which the contraceptive coverage requirement in those Guidelines will apply.

The moral objections at issue here, like the religious objections prompting exemptions dating back to the inception of the Mandate in 2011, may, consistent with the statutory provision, permissibly inform what HHS, through HRSA, decides to provide for and support in the Guidelines. Since the first rulemaking on this subject in 2011, the Departments have consistently interpreted the broad discretion granted to HRSA in section 2713(a)(4) as including the power to reconcile the ACA's preventive-services requirement with sincerely held views of conscience on the sensitive subject of contraceptive coverage—namely, by exempting churches and their integrated auxiliaries from the contraceptive-coverage Mandate. (*See* 76 FR at 46623.) As the Departments explained at that time, the HRSA Guidelines "exist solely to bind non-grandfathered group health plans and health insurance issuers with respect to the extent of their coverage of certain preventive services for women," and "it is appropriate that HRSA . . . takes into account the effect on the religious beliefs of [employers] if coverage of contraceptive services were required in [their] group health plans." *Id.* Consistent with that longstanding view, Congress's grant of discretion in section 2713(a)(4), and the lack of a mandate that contraceptives be covered or that they be covered without any exemptions or exceptions, lead the Departments to conclude that we are legally authorized to exempt certain entities or plans from a contraceptive Mandate if HRSA decides to otherwise include contraceptives in its Guidelines.

The Departments' conclusions are consistent with our interpretation of section 2713 of the PHS Act since 2010, when the ACA was enacted, and since the Departments started to issue interim final regulations implementing that section. The Departments have consistently interpreted section 2713(a)(4) to grant broad discretion to decide the extent to which HRSA will provide for, and support, the coverage of additional women's preventive care and screenings, including the decision to exempt certain entities and plans, and not to provide for or support the application of the Guidelines with respect to those entities or plans. The Departments created an exemption to the contraceptive Mandate when that Mandate was announced in 2011, and then amended and expanded the exemption and added an accommodation process in multiple rulemakings thereafter. The accommodation process requires the provision of coverage or payments for contraceptives to plan participants in an eligible organization's health plan by the organization's insurer or third party administrator. However, the accommodation process itself, in some cases, failed to require contraceptive coverage for many women, because—as the Departments acknowledged at the time—the enforcement mechanism for that process, section 3(16) of ERISA, does not provide a means to impose an obligation to provide contraceptive coverage on the third party administrator of self-insured church plans (see 80 FR 41323). Non-exempt employers participate in many church plans. Therefore, in both the previous exemption, and in the previous accommodation's application to self-insured church plans, the Departments have been choosing not to require contraceptive coverage for certain kinds of employers since the Guidelines were adopted. In doing so, the Departments have been acting contrary to commenters who contended the Departments had no authority to create exemptions under section 2713 of the PHS Act, or its incorporation into ERISA and the Code, and who contended instead that the Departments must enforce Guidelines on the broadest spectrum of group health plans as possible, even including churches (see, for example, 2012 final regulations at 77 FR 8726).

The Departments' interpretation of section 2713(a)(4) is confirmed by the ACA's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (see for

[10] See As (usage 2), *Oxford English Dictionary Online* (Feb. 2018) ("[u]sed to indicate by comparison the way something happens or is done").

example, 76 FR 46623). On the contrary, Congress carved out an exemption from section 2713 of the PHS Act (and from several other provisions) for grandfathered plans. In contrast, the grandfathering exemption is not applicable to many of the other provisions in Title I of the ACA—provisions previously referred to by the Departments as providing "particularly significant protections." (75 FR 34540). Those provisions include (from the PHS Act) section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime dollar limits; section 2712, which generally prohibits rescission of health coverage; section 2714, which extends dependent child coverage until the child turns 26; and section 2718, which imposes a minimum medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), and requires them to provide rebates to policyholders if that medical loss ratio is not met. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713.[11] Some commenters assert the exemptions for grandfathered plans are temporary, or were intended to be temporary, but as the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." *Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2764 n.10 (2014).

Some commenters argue that Executive Order 13535's reference to implementing the ACA consistent with certain conscience laws does not justify creating exemptions to contraceptive coverage in the Guidelines, because those laws do not specifically require exemptions in the Guidelines. The Departments, however, believe that they are acting consistent with Executive Order 13535 by creating exemptions using HRSA's authority under section 2713(a)(4), and the Departments' administrative authority over the implementation of section 2713(a) of the PHS Act. Executive Order 13535, issued upon the signing of the ACA, specified that "longstanding Federal laws to protect conscience . . . remain intact," including laws that protect holders of religious beliefs or moral convictions from certain requirements in health care contexts. Although the text of Executive Order 13535 does not require the expanded exemptions confirmed in these final rules, the expanded exemptions are, as explained below, consistent with longstanding federal laws to protect conscience objections, based on religious beliefs or moral convictions regarding certain health matters, and are consistent with the intent that the ACA be implemented in accordance with the conscience protections set forth in those laws.

Some commenters contended that, even though Executive Order 13535 refers to the Church Amendments, the intention of those statutes is narrow, should not be construed to extend to entities instead of to individuals, and should not be construed to prohibit procedures. But those comments mistake the Departments' position. The Departments are not construing the Church Amendments to require these exemptions, nor do the exemptions prohibit any procedures. Instead, through longstanding federal conscience statutes, Congress has established consistent principles concerning respect for sincerely held moral convictions in sensitive healthcare contexts.[12] Under those principles, and absent any contrary requirement of law, the Departments are offering exemptions for sincerely held moral convictions to the extent the Departments otherwise impose a contraceptive Mandate. These exemptions do not prohibit any services, nor authorize employers to prohibit employees from obtaining any services. The exemptions in the Moral IFC and these final rules simply refrain from imposing a federal mandate that employers cover contraceptives in their health plans even if they have sincerely held moral convictions against doing so.

Some commenters stated that the Supreme Court ruled that the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment. From this, commenters concluded that the exemptions for houses of worship and integrated auxiliaries are legally authorized, but that exemptions beyond those are not. But the Supreme Court did not rule on the question whether the exemptions provided for houses of worship and integrated auxiliaries were required by the First Amendment, and the Court did not say the Departments must apply the contraceptive Mandate unless RFRA prohibits us from doing so.

The appropriateness of including exemptions to protect moral convictions is informed by Congress's long history of providing exemptions for moral convictions, especially in certain health care contexts.

2. Congress's History of Protecting Moral Convictions

The Department received numerous comments about its decision in the Moral IFC to exercise its discretion to provide moral exemptions to, and an accommodation under, the contraceptive Mandate. Some commenters agreed with the Departments' decision in the Moral IFC, arguing that it is appropriate to exercise the Departments' discretion to protect moral convictions in light of Congress's history of protecting moral convictions in various contexts, especially concerning health care. Other commenters disagreed, saying that existing conscience statutes protecting moral convictions do not require these exemptions and, therefore, the exemptions should not be offered. Some commenters stated that because Congress has provided conscience protections, but did not specifically provide them in section 2713(a)(4), conscience protections are inappropriate in the implementation of that section. Still other commenters went further, disagreeing with conscience protections regarding contraceptives, abortions, or health care in general.

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on the most recent statements of Congress, along with nearly 50 years of statutes and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health coverage. Most recently, Congress expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act, 2018, Div. E, section 808, Public Law 115–141, 132 Stat. 348, 603 (Mar. 23, 2018); *see also*

[11] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," Henry J Kaiser Family Foundation (Sept. 19, 2017), *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[12] The Departments note that the Church Amendments are the subject of another, ongoing rulemaking process. *See* Protecting Statutory Conscience Rights in Health Care; Delegations of Authority, 83 FR 3880 (NPRM Jan. 26, 2018). Since the Departments are not construing the Amendments to require the religious exemptions, we defer issues regarding the scope, interpretation, and protections of the Amendments to HHS in that rulemaking.

Consolidated Appropriations Act, 2017, Div. C, section 808, Public Law 115–31 (May 5, 2017). The Departments consider it significant that Congress's most recent statements on the prospect of Government-mandated contraceptive coverage specifically intend that a conscience clause be included to protect moral convictions.

The Departments also consider significant the many statutes listed above, in section I—Background footnote 1, that show Congress's consistent protection of moral convictions alongside religious beliefs in the federal regulation of health care. These include laws such as the Church Amendments (dating back to 1973), which we discuss at length below, to the 2018 Consolidated Appropriations Act discussed above. Notably among those laws, and in addition to the Church Amendments, Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare + Choice (now Medicare Advantage) managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"). Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions." Consolidated Appropriations Act, 2018, Public Law 115–141, Division E, section 726(c); *see also* Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.[13]

The Departments disagree with commenters that suggested we should not consider Congress's history of protecting moral objections in certain health care contexts due to Congress's failure to explicitly include exemptions in section 2713(a)(4) itself. The argument by these commenters proves too much, since Congress also did not specifically require contraceptive coverage in section 2713 of the PHS Act. This argument would also negate not just these expanded exemptions, but the previous exemptions provided for houses of worship and integrated auxiliaries, and the indirect exemption for self-insured church plans that use the accommodation. Where Congress left so many matters concerning section 2713(a)(4) to agency discretion, the Departments consider it appropriate to implement these expanded exemptions in light of Congress's long history of respecting moral convictions in the context of certain federal health care requirements.

a. The Church Amendments' Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations because they had received federal funds. These sections of the U.S. Code are known as the Church Amendments, named after their primary sponsor, Senator Frank Church (D-Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions, not just religious beliefs. Among other things, the amendments protect the recipients of certain federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object "on the basis of religious beliefs or moral convictions," and they prohibit recipients of certain federal health funds from discriminating against any personnel "because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions" (42 U.S.C. 300a–7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to "any lawful health service," or to "any part of a health service program." (42 U.S.C. 300a–7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute "any lawful health service" or a "part of a health service program." As such, the protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court's decision in *Roe* v. *Wade*, 410 U.S. 113 (1973). Although the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens facilitate its exercise. Indeed, *Roe* favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared, "Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles." 410 U.S. at 144 & n.38 (1973). Likewise, in *Roe's* companion case, *Doe* v. *Bolton*, the Court observed that, under state law, "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure." 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions "obviously . . . afford appropriate protection." *Id.* at 198. As an Arizona court later put it, "a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either." *Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only *Roe* v. *Wade*, but also an instance where a federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D–IL) rose to ask that the amendment be changed to specify that it also protects objections to abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record records this discussion:

> Mr. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.
>
> One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or

[13] The Departments also note that, in protecting those individual and institutional health care entities that object to certain abortion-related services and activities regardless of the basis for such objection, the Coats-Snowe Amendment, PHS Act section 245 (42 U.S.C. 238n), and the Weldon Amendment, Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141, protect those whose objection is based on moral conviction.

participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.

As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?

Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words "or moral"?

Mr. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words "or moral conviction" were added after "religious belief." I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.

Mr. STEVENSON. The Senator's suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18

As the debate proceeded, Senator Church went on to quote *Doe* v. *Bolton*'s reliance on a Georgia statute that stated "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure." 119 Congr. Rec. S5722 (quoting 410 U.S. at 197–98). Senator Church added, "I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations." *Id.* Considering the scope of the protections, Senator Gaylord Nelson (D–WI) asked whether, "if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, 'We are not going to bother with this kind of procedure in this hospital,' would the pending amendment permit that?" 119 Congr. Rec. S5723. Senator Church responded that the amendment would not encompass such an objection. *Id.*

Senator James L. Buckley (C–NY), speaking in support of the amendment, added the following perspective:

Mr. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the recent Supreme Court decisions will likely unleash a series of court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic] [14] to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words "moral conviction," because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. S5723

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R–MA) [15] likewise observed that "the right of conscience has long been recognized in the parallel situation in which the individual's right to conscientious objector status in our selective service system has been protected" and "expanded by the Supreme Court to include moral conviction as well as formal religious belief." 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, "We are concerned here only with the right of moral conscience, which has always been a part of our national tradition." *Id.* at 4149.

These first sections of the Church Amendments, codified at 42 U.S.C. 300a–7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions, as well as those who object to such services on the basis of religious beliefs. And, as noted above, subsequent statutes add protections for moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion. *See* 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), Public Law 115–141.
- Protections for entities and individuals that object to providing or covering contraceptives. *See id.* at Div. E, Sec. 808; *id.* at Div. E, Sec. 726(c) (Financial Services and General Government Appropriations Act); *id.* at Div. K, Title III.
- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives. *See* 42 U.S.C. 290bb–36; 42 U.S.C. 1396a(w)(3); 42 U.S.C. 14406; 42 U.S.C. 18113 (adopted as part of the ACA).

The Departments believe that the intent behind Congress's protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports the Departments' decision in the Moral IFC and these final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

b. Court Precedents Relevant to These Expanded Exemptions

As reflected in the legislative history of the first Church Amendments, the Supreme Court has long afforded protection to moral convictions alongside religious beliefs. Indeed, Senator Church cited *Doe* v. *Bolton*, 410 U.S. 179, as a parallel instance of conscience protection and spoke of the Supreme Court generally giving "comparable treatment to deeply held moral convictions." Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court's protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as *Welsh* v. *United States*, 398 U.S. 333 (1970), which the Supreme Court had decided just three years earlier.

Welsh involved what is perhaps the Government's paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on "religious training and belief," that protection would also extend to avowedly non-religious objections to war held with the same moral strength.

[14] The Senator might have meant "[forced] . . . against his will."

[15] Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

Id. at 343. The Court declared, "[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual 'a place parallel to that filled by . . . God' in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as much entitled to a 'religious' conscientious objector exemption . . . as is someone who derives his conscientious opposition to war from traditional religious convictions."

In the context of this particular Mandate, it is also worth noting that, in *Hobby Lobby*, Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan's opinion in *Welsh*, 398 U.S. at 357–58, in support of her statement that "[s]eparating moral convictions from religious beliefs would be of questionable legitimacy." 134 S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious beliefs constitute an illegitimate "separat[ion]" of moral convictions, nor do the Departments assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress's intent in the Church Amendments and in later federal statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

c. Conscience Protections in Other Federal and State Contexts

The tradition of protecting moral convictions in certain health contexts is not limited to laws passed by Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.[16] Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs in particular circumstances. The Equal Employment Opportunity Commission has consistently protected "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views" alongside religious views under the "standard [] developed in *United States* v. *Seeger*, 380 U.S. 163 (1965) and *[Welsh]*." 29 CFR 1605.1. The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so "is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such participation or attendance contrary to medical ethics." 28 CFR 26.5.[17]

Forty-five states have health care conscience protections covering objections to abortion; several of these also cover sterilization or contraception.[18] Most of those state laws protect objections based on "moral," "ethical," or "conscientious" grounds in addition to "religious" grounds. Particularly in the case of abortion, some federal and state conscience laws do not require any specified motive for the objection. 42 U.S.C. 238n; Consolidated Appropriations, 2018, Public Law 115–141, Div. H, section 507(d).

These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts. The contraceptive Mandate implicates that governmental interest. Many persons and entities object to the Mandate in part because they consider some forms of FDA-approved contraceptives to be morally equivalent to abortion due to the possibility that such items may prevent the implantation of a human embryo after fertilization.[19] The Supreme Court, in describing family business owners with religious objections, explained that "[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions." *Hobby Lobby*, 134 S. Ct. at 2751. Based on pleadings in the litigation, all of the litigants challenging the Mandate and asserting purely non-religious objections share this view. And as Congress has implicitly recognized in providing health care conscience protections pertaining to sterilization, contraception, and other health care services and practices, individuals or entities may have additional moral objections to contraception.[20]

d. Founding Principles

The Departments also look to guidance from, and draw support for the Moral IFC and these final rules from, the broader history of respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. In supporting the protection of conscience based on non-religious moral convictions, Senator Buckley declared "[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred." Representative Heckler similarly stated that "the right of moral conscience . . . has always been a part of our national tradition." This tradition is reflected, for example, in a letter President George Washington wrote saying that "[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: A policy worthy of imitation. All possess alike liberty of conscience and immunities of

[16] *See, for example*, 42 CFR 422.206 (declaring that the general Medicare Advantage rule "does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds."); 42 CFR 438.102 (declaring that information requirements do not apply "if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds"); 48 CFR 1609.7001 ("health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs."); 48 CFR 352.270–9 ("Non-Discrimination for Conscience" clause for organizations receiving HIV or Malaria relief funds).

[17] *See also* 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA's request will depend in part on "[c]ultural, religious, or moral objections to the request").

[18] According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). "Refusing to Provide Health Services," The Guttmacher Institute (June 1, 2017), *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services*.

[19] FDA, "Birth Control," U.S. Food and Drug Administration (Mar. 6, 2018), *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm* (various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization, but "may also work . . . by preventing attachment (implantation) to the womb (uterus)" of a human embryo after fertilization).

[20] *See supra* note 1.

citizenship." [21] Thomas Jefferson similarly declared that "[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority." [22] Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience "the most sacred of all property," and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that "the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed." [23]

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context, and the Departments do not suggest that the specific protections offered in the Moral IFC and these final rules would be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These final rules do not address in any way how the Government would balance its interests with respect to other health services not encompassed by the contraceptive Mandate.[24] Instead, the Departments highlight this tradition of respect for conscience from the Nation's Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4), while protecting conscience in the exercise of moral convictions. The Departments believe that these final rules are consistent both with the American tradition of respect for conscience and with Congress's history of providing conscience protections in the kinds of health care matters involved in this Mandate.

e. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in these expanded exemptions and accommodation in these final rules, is consistent with recent executive orders. President Trump's Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for "religious" beliefs, but for "conscience." We interpret that term to include both religious beliefs and moral convictions. Moreover, President Trump's first Executive Order, E.O. 13765, declared that "the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." The exemption and accommodation adopted in these final rules relieves a regulatory burden imposed on entities with moral convictions opposed to providing certain contraceptive coverage and is therefore consistent with both Executive Orders.

f. Litigation Concerning the Mandate

The Departments have further taken into consideration the litigation surrounding the Mandate in exercising their discretion to adopt the exemption in these final rules. Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. *See March for Life* v. *Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court affirmed a district court ruling that allows the previous regulations to be imposed in a way that affects the moral convictions of a small nonprofit pro-life organization and its employees. *See Real Alternatives* v. *Sec'y. Dep't of Health & Human Servs.*, 867 F.3d 338 (3d Cir. 2017). The Departments' litigation of these cases has thus led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations, issuers, third party administrators, and employees and beneficiaries. The organizations that have sued seeking a moral exemption have adopted longstanding moral tenets opposed to certain FDA-approved contraceptives, and hire only employees who share this view. As a result, it is reasonable to conclude that employees of these organizations would not benefit from the Mandate. Thus, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, as well as the legal requirement to comply with permanent injunctive relief currently imposed in *March for Life*, provide substantial reasons for the Departments to protect moral convictions through these final rules. Although, as discussed below, the Departments assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, the Departments know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, the Departments consider it appropriate to issue the protections set forth in these final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so the Departments, too, believe that "our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government" in this situation. *See* 119 Congr. Rec. S5717–18.

The litigation concerning the Mandate has also underscored how important it is for the Government to tread carefully when engaging in regulation concerning sensitive health care areas. As demonstrated by the litigation, as well as the public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that certain contraceptive items may cause early abortions. Providing conscience protections advances the ACA's goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in *Hobby Lobby* declared that, if HHS requires owners of businesses to

[21] Letter from George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790) (available at *https://founders.archives.gov/documents/Washington/05-06-02-0135*).

[22] Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809) (available at *https://founders.archives.gov/documents/Jefferson/99-01-02-9714*).

[23] James Madison, "Essay on Property" (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

[24] As the Supreme Court stated in *Hobby Lobby*, the Court's decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer's religious beliefs. Nor does the Court's opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

cover procedures that the owners "could not in good conscience" cover, such as abortion. "HHS would effectively exclude these people from full participation in the economic life of the Nation." 134 S. Ct. at 2783. That sort of outcome is one the Departments wish to avoid. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) in a way that respects the moral convictions of Americans so that they are freer to engage in "full participation in the economic life of the Nation." The exemptions in these final rules do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

3. Whether Moral Exemptions Should Exist, and Whom They Should Cover

As noted above, the Department received comments expressing diverse views as to whether exemptions based on moral convictions should exist and, if so, whom they should cover.

Some commenters supported the expanded exemptions and accommodation in the Moral IFC, and the choice of entities and individuals to which they applied. They stated the expanded exemptions and accommodation would be an appropriate exercise of discretion and would be consistent with moral exemptions Congress has provided in many similar contexts. Similarly, commenters stated that the accommodation would be an inadequate means to resolve moral objections and that the expanded exemptions are needed. They contended that the accommodation process was objectionable because it was another method of complying with the Mandate, its self-certification or notice involved triggering the very contraceptive coverage that organizations objected to, and the coverage for contraceptive services "hijacked" or flowed in connection with the objecting organizations' health plans. The commenters contended that the seamlessness cited by the Departments between contraceptive coverage and an accommodated plan gives rise to moral objections that organizations would not have with an expanded exemption. Commenters also stated that, with respect to non-profit organizations that have moral objections and only hire persons who agree with those objections, the Mandate serves no legitimate government interest because the mandated coverage is neither wanted nor used and, therefore, would yield no benefits—it would only suppress the existence of non-profit organizations holding those views.

Several other commenters stated that the exemptions were still too narrow. They asked that the exemptions set forth in these final rules be as broad as the exemptions set forth in the Religious IFC concerning sincerely held religious beliefs. Some of these commenters also asked that HHS withdraw its Mandate of contraceptive coverage from the Guidelines entirely. They contended that fertility and pregnancy are generally healthy conditions, not diseases that are appropriately the target of a preventive health service; that contraceptives can pose medical risks for women; and that studies do not show that contraceptive programs reduce abortion rates or unintended pregnancies. Some commented that many women report that they sought an abortion because their contraception failed. Some other commenters contended that, to the extent the Guidelines require coverage of certain drugs and devices that may prevent implantation of an embryo after fertilization, they require coverage of items that are abortifacient and, therefore, violate federal conscience protections such as the Weldon Amendment, Consolidated Appropriations Act, 2017, Public Law 115–31, Div. H, § 507(d).

Other commenters contended that the exemptions in the Moral IFC were too broad. Some of these commenters expressed concern about the prospect of publicly traded for-profit entities also being afforded a moral exemption. One such commenter commented that allowing publicly traded for-profit entities a moral exemption could cause instability and confusion, as leadership changes at such a corporation may effectively change the corporation's eligibility for a moral exemption. Still others stated that the Departments should not exempt various kinds of entities such as businesses, issuers, or nonprofit entities, arguing that only individuals, not entities, can possess moral convictions. Some commenters were concerned that providing moral exemptions would contribute to population growth and related societal woes. Other commenters contended the exemptions and accommodation should not be expanded, but should remain the same as they were in the July 2015 final regulations (80 FR 41318), which did not encompass moral convictions. Other commenters stated that the Departments should not provide exemptions, but merely an accommodation process, to resolve moral objections to the Mandate.

Some commenters objected to providing any exemption or accommodation for moral objections at all. Some of these commenters contended that even the previous regulations allowing an exemption and accommodation were too broad and that no exemptions to the Mandate should exist, in order that contraceptive coverage would be provided to as many women as possible. Other commenters did not go that far, but rejected the idea of exemptions or an accommodation based on moral convictions, contending that such exemptions or accommodation would contribute to population growth and related social woes. Some of these commenters also contended that the exemption in the Moral IFC would constitute an exemption covering every business and non-profit organization.

After considering these comments, and although the previous Administration declined to afford any exemption based on moral convictions, the Departments have concluded that it is appropriate to provide moral exemptions and access to the accommodation, as set forth in these final rules. Congress did not mandate contraceptive coverage, nor provide any explicit guidance about incorporating conscience exemptions into the Guidelines. But as noted above, it is a long-standing Congressional practice to provide consistent exemptions for both religious beliefs and moral convictions in many federal statutes in the health care context, and specifically concerning issues such as abortion, sterilization, and contraception. It is not clear to the Departments that, if Congress had expressly mandated contraceptive coverage in the ACA, it would have done so without providing for similar exemptions. Therefore, the Departments consider it appropriate, to the extent we impose a contraceptive Mandate by the exercise of agency discretion, that we also include an exemption for the protection of moral convictions in certain cases. The exemptions finalized in these final rules are generally consistent with the scope of exemptions that Congress has established in similar contexts. As noted above, the Departments consider the exemptions in these final rules consistent with the intent of Executive Order 13535. The Departments also wish to avoid the stark disparity that may result from respecting religious objections to providing contraceptive coverage among certain entities and individuals, but not respecting parallel objections for moral convictions possessed by any entities and

individuals at all because those objections are not specifically religious.

In addition, the Departments note that a significant majority of states either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[25] Although the practice of states is by no means a limit on the discretion delegated to HRSA by the ACA, nor a statement about what the Federal Government may do consistent with other limitations in federal law, such state practices can inform the Departments' view that it is appropriate to provide conscience protections when exercising agency discretion.

The Departments decline to use these final rules to remove the contraceptive Mandate altogether, such as by declaring that HHS acting through HRSA shall not include contraceptives in the list of women's preventive services in Guidelines issued under section 2713(a)(4). HRSA's Guidelines were not issued, ratified, or updated through the regulations that preceded the Moral IFC and these final rules. Those Guidelines were issued in separate processes in 2011 and 2016, directly by HRSA, after consultation with external organizations that operated under cooperative agreements with HRSA to consider the issue, solicit public comment, and provide recommendations. The regulations preceding these final rules attempted only to restate the statutory language of section 2713 in regulatory form, and delineate what exemptions and accommodations would apply if HRSA listed contraceptives in its Guidelines. We decline to use these final rules to direct the separate process that HRSA uses to determine what specific services are listed in the Guidelines generally. Some commenters stated that if contraceptives are not removed from the Guidelines entirely, entities or individuals with moral objections might not qualify for the exemptions or accommodation. As discussed below, however, the exemptions in these rules include a broad range of entities and individuals of whom we have notice may object based on moral convictions. The Departments are not aware of specific employers or individuals whose moral convictions would still be violated by compliance with the Mandate after the issuance of the Moral IFC and these final rules.

Some commenters stated that HRSA should remove contraceptives from the Guidelines because the Guidelines have not been subject to the notice and comment process under the Administrative Procedure Act. Some commenters also contended that the Guidelines should be amended to omit items that may prevent (or possibly dislodge) the implantation of a human embryo after fertilization, in order to ensure consistency with conscience provisions that prohibit requiring plans to pay for or cover abortions. Whether and to what extent the Guidelines continue to list contraceptives, or items considered to prevent implantation of an embryo, for entities not subject to exemptions and an accommodation, and what process is used to include those items in the Guidelines, is outside the scope of these final rules. These final rules focus on what moral exemptions and accommodation shall apply if Guidelines issued under section 2713(a)(4) include contraceptives or items considered to be abortifacient.

Members of the public that support or oppose the inclusion of some or all contraceptives in the Guidelines, or wish to comment concerning the content and process of developing and updating the Guidelines, are welcome to communicate their views to HRSA, at *wellwomancare@hrsa.gov*.

The Departments also conclude that it would be inadequate to merely attempt to amend or expand the accommodation process to account for moral objectors, instead of providing the exemptions. In the past, the Departments stated in our regulations and court briefs that the previous accommodation required contraceptive coverage in a way that is "seamless" with the coverage provided by the objecting employer. As a result, in significant respects, the accommodation process did not actually accommodate the objections of many entities, as indicated by many entities with religious objections. The Departments have attempted to identify an accommodation that would eliminate the religious plaintiffs' objections, including seeking public comment through a Request For Information, 81 FR 47741 (July 26, 2016), but stated in January 2017 that we were unable to develop such an approach at that time.[26] Just as the Departments continue to believe merely amending the accommodation process would not adequately address religious objections to compliance with the Mandate, we do not believe doing so would adequately address similar moral objections. Furthermore, the few litigants raising non-religious moral objections have been non-profit organizations that assert they only hire persons who share the employers' objection to contraceptive coverage. Consequently, the Departments conclude that the most appropriate approach to resolve these concerns is to provide the exemptions set forth in the Moral IFC and these final rules. These final rules also finalize the modifications to the accommodation process to make it available to entities with moral objections, without forcing such entities to choose between compliance with either the Mandate or the accommodation.

Some commenters expressed concern over the lack of a definition of "moral convictions" in the Moral IFC, arguing that, without a definition, any objection could be encompassed by the exemptions even if it is not based on moral convictions. The Departments did not adopt a regulatory definition of "moral convictions" in the Moral IFC, and have decided not to adopt such a definition in response to public comments at this time. Nevertheless, the Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in the Moral IFC and these final rules. Neither these final rules or the Moral IFC, nor the Church Amendments or other Federal health care conscience statutes, define "moral convictions" (nor do they define "religious beliefs"). But in issuing these final rules, we adopt the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as *Welsh* to support the addition of language protecting moral convictions. In protecting moral convictions in parallel to religious beliefs, *Welsh* describes moral convictions warranting such protection as ones: (1) That the "individual deeply and sincerely holds"; (2) "that are purely ethical or moral in source and content"; (3) "but that nevertheless impose upon him a duty"; (4) and that "certainly occupy in the life of that individual a place parallel to that filled by . . . God' in traditionally religious persons," such

[25] *See* "Insurance Coverage of Contraceptives," The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives*.

[26] *See* Departments of Labor, Health and Human Services, and the Treasury, FAQs About Affordable Care Act Implementation Part 36, (Jan. 9, 2017), *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf* ("the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage").

that one could say "his beliefs function as a religion in his life." 398 U.S. at 339–40. As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises "capriciously." Instead, along with the requirement that protected moral convictions must be "sincerely held," this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

While moral convictions are the sort of principles that, in the life of an individual, occupy a place parallel to religion, sincerely held moral convictions can also be adopted by corporate bodies, not merely by individuals. Senators Church and Nelson, while discussing the fact that opposition to abortion or sterilization on the basis of "moral questions" does not include capricious opposition to abortion for no reason at all, were specifically talking about opposition to abortion by corporate entities: A "hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise." [27] Corporate bodies operate by the decision-making actions of individuals. Thus, if individuals act in the governance of a corporate body so as to adopt a position for that body of adopting moral convictions against coverage of contraceptives, such an entity can be considered to have an objection to contraceptive coverage on the basis of sincerely held moral convictions.

4. The Departments' Rebalancing of Government Interests

The Departments also received comments on their rebalancing of interests as expressed and referenced in the Moral IFC. Some public commenters agreed with the Departments' conclusion that our interest in ensuring contraceptive coverage does not preclude the Departments from offering exemptions and an accommodation for entities, plans, and individuals with a qualifying objection to contraceptive coverage based on moral convictions. Some public commenters pointed out that protecting moral convictions serves to respect not only the interests of certain persons to access contraceptives, but also the interests of other persons to participate in a health coverage market consistent with their moral convictions. Other commenters disagreed with this rebalancing, and contended that the interest of women in receiving contraceptive coverage without cost-sharing is so great that it overrides private interests to the contrary, such that the government should or must force private entities to provide this coverage to other private citizens.

The Departments agree with the commenters who stated that the governmental interest in requiring contraceptive coverage does not override the interest in protecting moral convictions and does not make these expanded exemptions inappropriate. For additional discussion of the Government's balance of interests as applicable to religious beliefs, see section II.C.2.b. of the companion final rules concerning religious exemptions published by the Departments contemporaneously with these final rules elsewhere in today's **Federal Register**. There, and in the Religious and Moral IFCs, the Departments acknowledged the reasons why the Departments have changed the policies and interpretations previously adopted with respect to the Mandate and the governmental interests underlying it. For parallel reasons, the Departments believe the Government's legitimate interests in providing for contraceptive coverage do not require the Departments to violate sincerely held moral convictions while implementing the Guidelines. The Departments likewise believe Congress did not set forth interests that require us to violate sincerely held moral convictions if we otherwise require contraceptive coverage in our discretionary implementation of the women's preventive services Guidelines under section 2713(a)(4).

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4), added to the PHS Act in 2010. The Departments' expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after considering public comments on various sides of the issue, and reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant federal law, the Departments have determined that affording the exemptions to protect moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to invoke these exemptions and accommodation may be small, the Departments believe that it is important to provide such protection, given the long-standing recognition of such protections in law and regulation in the health care and health insurance contexts. The Moral IFC and these final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, including through such programs as Medicaid and Title X. The Departments also note that the exemptions created here, like the exemptions created by the previous Administration, do not burden third parties to a degree that counsels against providing the exemptions, as discussed below.

5. Burdens on Third Parties

The Department received a variety of comments about the effect that the exemptions and accommodation based on moral convictions would have on third parties. Some commenters stated that the exemptions and accommodation do not impose an impermissible or unjustified burden on third parties, including on women who might otherwise receive contraceptive coverage with no cost sharing. Other commenters disagreed, asserting that the exemptions unacceptably burden women who might lose contraceptive coverage as a result. They contended the exemptions may remove contraceptive coverage, causing women to have higher contraceptive costs, fewer contraceptive options, less ability to use contraceptives more consistently, more

[27] Nor was this recognition of the need to protect organizations that object to performance of certain health care procedures on the basis of moral conviction limited to the Church Amendments' legislative history. The first of the Church Amendments provides, in part, that the receipt of certain federal funds "by any individual or entity does not authorize any court or any public official or other public authority to require— . . . (2) such entity to—(A) make its facilities available for the performance of any sterilization procedure or abortion if the performance of such procedure or abortion in such facilities is prohibited by the entity on the basis of religious beliefs or moral convictions, or (B) provide any personnel for the performance or assistance in the performance of any sterilization procedure or abortion if the performance or assistance in the performance of such procedures or abortion by such personnel would be contrary to the religious beliefs or moral convictions of such personnel." 42 U.S.C. 300a–7(b).

unintended pregnancies,[28] births spaced more closely, and workplace, economic, or societal inequality. Still other commenters took the view that other laws or protections, such as in the First or Fifth Amendments, prohibit the expanded exemptions, which those commenters view as prioritizing conscientious objection of exempted entities over the conscience, choices, or religious liberty of women who would not receive contraceptive coverage where an exemption is used. Some commenters disagreed and said the exemptions do not violate laws and constitutional protections, nor do they inappropriately prioritize the conscience of exempted entities over those of third parties.

The Departments note that the exemptions in the Moral IFC and these final rules, like the exemptions created by the previous Administration, do not impermissibly burden third parties. Initially, the Departments observe that these rules do not create a governmental burden; rather, they relieve a governmental burden. The ACA did not impose a contraceptive coverage requirement. Agency discretion was exercised to include contraceptives in the Guidelines issued under section 2713(a)(4). That decision is what created and imposed a governmental burden. These rules simply relieve part of that governmental burden. If some third parties do not receive contraceptive coverage from private parties whom the government chooses not to coerce, that result exists in the absence of governmental action—it is not a result the government has imposed. Calling that result a governmental burden rests on an incorrect presumption: That the government has an obligation to force private parties to benefit those third parties, and that the third parties have a right to those benefits. Congress did not create a right to receive contraceptive coverage from other private citizens through section 2713 of the PHS Act, other portions of the ACA, or any other statutes it has enacted. Although some commenters also contended such a right might exist under treaties the Senate has ratified or the Constitution, the Departments are not aware of any source demonstrating that the Constitution or a treaty ratified by the Senate creates a right to receive contraceptive coverage from other private citizens.

The fact that the government at one time exercised its administrative discretion to require private parties to provide coverage to which they morally object, to benefit other private parties, does not prevent the government from relieving some or all of the burden of that Mandate. Otherwise, any governmental coverage requirement would be a one-way ratchet. In the Moral IFC and these final rules, the government has simply restored a zone of freedom where it once existed. There is no statutory or constitutional obstacle to the government doing so, and the doctrine of third party burdens should not be interpreted to impose such an obstacle. Such an interpretation would be especially problematic given the millions of women, in a variety of contexts, whom the Mandate does not ultimately benefit, notwithstanding any expanded exemptions—including through the grandfathering of plans, the previous religious exemptions, and the failure of the accommodation to require delivery of contraceptive coverage in various self-insured church plan contexts.

In addition, the Government is under no constitutional obligation to fund contraception. *Cf. Harris* v. *McRae*, 448 U.S. 297 (1980) (holding that, although the Supreme Court has recognized a constitutional right to abortion, there is no constitutional obligation for government to pay for abortions). Even more so may the government refrain from requiring private citizens, in violation of their moral convictions, to cover contraception for other citizens. *Cf. Rust* v. *Sullivan*, 500 U.S. 173, 192–93 (1991) ("A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity."). The constitutional rights of liberty and privacy do not require the government to force private parties to provide contraception to other citizens and do not prohibit the government from protecting moral objections to such governmental mandates, especially where, as here, the Mandate is not an explicit statutory requirement.[29] The Departments do not believe that the Constitution prohibits offering the expanded exemptions in these rules.

Some commenters objected that the exemptions would violate the Establishment Clause of the First Amendment. The Moral IFC and these final rules create exemptions for moral convictions, not religious beliefs, and they do so for the same neutral purposes for which Congress has created similar exemptions for over four decades. Not only do these final rules not violate the Establishment Clause, but the Departments' decision to provide the exemptions and accommodation for moral convictions, instead of limiting the exemptions to identical objections based on religious beliefs, further demonstrates that neither the purpose nor the effect of these exemptions is to establish religion. The Establishment Clause does not force the Department to impose a contraceptive Mandate in violation of the moral convictions of entities and individuals protected by these rules.

American governmental bodies have, in many instances, refrained from requiring certain private parties to cover contraceptive services for other private parties. From 1789 through 2012 (when HRSA's Guidelines went into effect), there was no federal women's preventive services coverage mandate imposed nationally on health insurance and group health plans. The ACA did not require contraceptives to be included in HRSA's Guidelines, and it did not require any preventive services required under section 2713 of the PHS Act to be covered by grandfathered plans. Many states do not impose contraceptive coverage mandates, or they offer religious, and in some cases moral, exemptions to the requirements of such coverage mandates—exemptions that have not been invalidated by federal or state courts. The Departments, in previous regulations, exempted houses of worship and integrated auxiliaries from the Mandate. The Departments then issued a temporary enforcement safe harbor allowing religious nonprofit groups to not provide contraceptive coverage under the Mandate for almost two additional years. The Departments further expanded the houses of worship and integrated auxiliaries exemption through definitional changes. And the Departments created an accommodation process under which many women in self-insured church plans may not ultimately receive contraceptive coverage. The Departments are not aware of federal courts declaring that the exemptions, safe harbor, or accommodations gave rise to third party burdens that required the government to mandate contraceptive coverage by entities eligible for an exemption or accommodation. In addition, many organizations have not been subject to the Mandate in practice because of injunctions they received through litigation, protecting them from federal imposition of the Mandate, including

[28] Some commenters attempted to quantify the costs of unintended pregnancy, but were unable to provide estimates with regard to the number of women that this exemption may affect.

[29] *See, for example, Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011) ("[A] woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.").

under several recently entered permanent injunctions that will apply regardless of the issuance of these final rules.

Commenters offered various assessments of the impact these rules might have on state or local governments. Some commenters stated that the expanded exemptions will not burden state or local governments, or that such burdens should not prevent the Departments from offering those exemptions. Others commenters stated that if the Departments provide expanded exemptions, states or local jurisdictions may face higher costs in providing birth control to women through government programs. The Departments consider it appropriate to offer expanded exemptions, notwithstanding the objection of some state or local governments. Until 2012, there was no federal mandate of contraceptive coverage across health insurance and health plans nationwide. The ACA did not require a contraceptive Mandate, and its discretionary creation by means of HRSA's Guidelines does not translate to a benefit that the federal government owes to state or local governments. The various situations recited in the previous paragraph, in which the federal government has not imposed contraceptive coverage, have not been deemed to cause a cognizable injury to state or local governments. The Departments find no legal prohibition on finalizing these final rules based on the allegation of an impact on state or local governments, and disagree with the suggestion that once having exercised our discretion to deny exemptions—no matter how recently or incompletely—the Departments cannot change course if some state and local governments believe they are receiving indirect benefits from the previous decision.

In addition, the exemptions at issue here are available only to a tiny fraction of entities to which the Mandate would otherwise apply—those with qualifying moral objections. Public comments did not provide reliable data on how many entities would use these expanded moral exemptions, in which states women in those plans would reside, how many of those women would qualify for or use state and local government subsidies of contraceptives as a result, or in which states such women, if they are low income, would go without contraceptives and potentially experience unintended pregnancies that state Medicaid programs would potentially have to cover. As noted below, at least one study [30] has concluded the Mandate caused no clear increase in contraceptive use; one explanation proposed by the authors of the study is that women eligible for family planning from safety net programs were already receiving free or subsidized contraceptive access through them, notwithstanding the Mandate's effects on the overall market. Some commenters who opposed the exemptions admitted that this information is unclear at this stage; other commenters that estimated considerably more individuals and entities would seek an exemption also admitted the difficulty of quantifying estimates. In addition, the only entities that have brought suit based on their moral objections to the Mandate are non-profit entities that have said they only hire persons who share their objections and do not use the contraceptives to which their employers object, so it is unlikely that exemptions for those entities would have any impact on safety net programs. Below, we predict that a small number of additional nonprofit and closely held for-profit entities will use the exemptions based on moral convictions. In light of the limited evidence of third party or state and local government impact of these final rules, the Departments consider it an appropriate policy option to provide the exemptions.

Some commenters contended that the exemptions would constitute unlawful sex discrimination, such as under section 1557 of the Affordable Care Act, Title VII of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, or the Fifth Amendment. Some commenters suggested the expanded exemptions would discriminate on bases such as race, disability, or LGBT status, or that they would disproportionately burden certain persons in such categories.

But these rules do not discriminate or draw any distinctions on the basis of sex, pregnancy, race, disability, socio-economic class, LGBT status, or otherwise, nor do they discriminate on any unlawful grounds. The exemptions in these rules do not authorize entities to comply with the Mandate for one person, but not for another person, based on that person's status as a member of a protected class. Instead, they allow entities that have sincerely held moral objections to providing some or all contraceptives included in the Mandate to not be forced to provide coverage of those items to anyone.

Those commenters' contentions about discrimination are unpersuasive for still additional reasons. First, Title VII is applicable to discrimination committed by employers, and these final rules have been issued in the government's capacity as a regulator of group health plans and group and individual health insurance, not in its capacity as an employer. *See also In Re Union Pac. R.R. Emp't Practices Litig.*, 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII "does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women"). Second, these rules create no disparate impact. The women's preventive service mandate under section 2713(a)(4), and the contraceptive Mandate promulgated under such preventive services mandate, already inure to the specific benefit of women—men are denied any benefit from section 2713(a)(4). Both before and after these rules are in effect, section 2713(a)(4) and the Guidelines issued under that section treat women's preventive services in general, and female contraceptives specifically, more favorably than they treat male preventive services or contraceptives.

It is simply not the case that the government's implementation of section 2713(a)(4) is discriminatory against women because exemptions encompass moral objections. The previous rules, as discussed elsewhere herein, do not require contraceptive coverage in a host of plans, including grandfathered plans, plans of houses of worship and integrated auxiliaries, and—through inability to enforce the accommodation on certain third party administrators—plans of many religious non-profits in self-insured church plans. Below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. In this context, the Departments do not believe that an adjustment to discretionary Guidelines for women's preventive services concerning contraceptives constitutes unlawful sex discrimination. Otherwise, anytime the government exercises its discretion to provide a benefit that is specific to women (or specific to men), it would constitute sex discrimination for the government to reconsider that benefit. Under that theory, *Hobby Lobby* itself, and RFRA (on which *Hobby Lobby*'s holding was based), which provided a religious exemption to this Mandate for many businesses, would be deemed discriminatory against women

[30] M.L. Kavanaugh et al., "Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014.", 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

because the underlying women's preventive services requirement is a benefit for women, not for men. Such conclusions are not consistent with legal doctrines concerning sex discrimination.

It is not clear that these expanded exemptions will significantly burden women most at risk of unintended pregnancies. Some commenters stated that contraceptives are often readily accessible at relatively low cost. Other commenters disagreed. Some commenters objected that the Moral IFC's estimate of a $584 yearly cost of contraceptives for women was too low. But some of those same commenters provided similar estimates, citing sources claiming that birth control pills can cost up to $600 per year, and stated that IUDs, which can last 3 to 6 years or more,[31] can cost $1,100 (that is, less than $50 per month over the duration of use). Some commenters stated that, for lower income women, contraceptives and related education and counseling can be available at free or low cost through government programs (federal programs offering such services include, for example, Medicaid, Title X, community health center grants, and Temporary Assistance for Needy Families (TANF)). Other commenters contended that many women in employer-sponsored coverage might not qualify for those programs, although that sometimes occurs because their incomes are above certain thresholds or because the programs were not intended to absorb privately covered individuals. Some commenters observed that contraceptives may be available through other sources, such as a plan of another family member, and that the expanded exemptions will not likely encompass a very large segment of the population otherwise benefitting from the Mandate. Other commenters disagreed, emphasizing that income and eligibility thresholds could prevent some women from receiving contraceptives through certain government programs if they were no longer covered in their group health plans or health insurance plans.

The Departments do not believe that such differences make it inappropriate to issue the expanded exemptions set forth in these rules. As explained more fully below, the Departments estimate that nearly all women of childbearing age in the country will be unaffected by these exemptions. Moreover, the Departments note that the HHS Office of Population Affairs, within the Office of the Assistant Secretary for Health, has recently issued a proposed rule to amend the regulations governing its Title X family planning program. The proposed rule would amend the definition of "low income family"—individuals eligible for free or low cost contraceptive services—to include women who are unable to obtain certain family planning services under their employer-sponsored health coverage due to their employers' religious beliefs or moral convictions. (83 FR 25502). If that rule is finalized as proposed, it would further reduce any potential effect of these final rules on women's access to contraceptives.

Some commenters stated that the expanded exemptions would violate section 1554 of the ACA. That section says the Secretary of HHS "shall not promulgate any regulation" that "creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care," "impedes timely access to health care services," "interferes with communications regarding a full range of treatment options between the patient and the provider," "restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions," "violates the principles of informed consent and the ethical standards of health care professionals," or "limits the availability of health care treatment for the full duration of a patient's medical needs." 42 U.S.C. 18114. Such commenters urged, for example, that the Moral IFC created unreasonable barriers to the ability of individuals to obtain appropriate medical care, particularly in areas they said may have a disproportionately high number of entities likely to take advantage of the exemption.

The Departments disagree with these comments about section 1554 of the ACA. The Departments issued previous exemptions and accommodations that allowed various plans to not provide contraceptive coverage on the basis of religious objections; multiple courts considered those regulations; and while many ruled that entities did not need to provide contraceptive coverage, none ruled that the exemptions or accommodations in the regulations violated section 1554 of the ACA. Moreover, the decision not to impose a governmental mandate is not the creation of a "barrier," especially when that mandate requires private citizens to provide services to other private citizens. This would turn the assumptions of the United States' system of government on its head. *See, for example,* U.S. Constitution, Ninth Amendment. Section 1554 of the ACA likewise does not require the Departments to require coverage of, or to keep in place a requirement to cover, certain services, including contraceptives, that was issued pursuant to HHS's exercise of discretion under section 2713(a)(4). Nor does section 1554 of the ACA prohibit the Departments from providing exemptions to relieve burdens on moral convictions, or as is the case here, from refraining to impose the Mandate in cases where moral convictions would be burdened by the Mandate. Moral exemptions from federal mandates in certain health contexts, including sterilization, contraception, or items believed to be abortifacient, have existed in federal laws for decades. Some of those laws were referenced by President Obama in signing Executive Order 13535. In light of that Executive Order and Congress's long history of providing exemptions for moral convictions in the health context, providing moral exemptions is a reasonable administrative response to this federally mandated burden, especially since the burden itself is a subregulatory creation that does not apply in various contexts.

In short, we do not believe sections 1554 or 1557 of the ACA, other nondiscrimination statutes, or any constitutional doctrines, create an affirmative obligation to create, maintain, or impose a Mandate that forces covered entities to provide coverage of preventive contraceptive services in health plans. The ACA's grant of authority to HRSA to provide for, and support, the Guidelines is not transformed by any of the laws cited by commenters into a requirement that, once those Guidelines exist, they can never be reconsidered, or amended because doing so would only affect women's coverage or would allegedly impact particular populations disparately.

In summary, members of the public have widely divergent views on whether the exemptions in the Moral IFC and these final rules are good public policy. Some commenters stated that the exemptions would burden workers, families, and the economic and social stability of the country, and interfere with the physician-patient relationship. Other commenters disagreed, favoring the public policy behind the exemption, and arguing that the exemption would not interfere with the physician-patient relationship. The Departments have determined that these final rules are an appropriate exercise of public policy discretion. Because of the importance of the moral convictions being accommodated, the limited impact of these final rules, and uncertainty about

[31] *See, for example,* "IUD," Planned Parenthood, *https://www.plannedparenthood.org/learn/birth-control/iud.*

the impact of the Mandate overall according to some studies, the Departments do not believe these final rules will have any of the drastic negative consequences on third parties or society that some opponents of these rules have suggested.

6. Interim Final Rulemaking

The Departments received several comments about the decision to issue the Moral IFC as interim final rules with request for comments, instead of as a notice of proposed rulemaking. Several commenters asserted that the Departments had the authority to issue the Moral IFC in that way, agreeing with the Departments that there was explicit statutory authority to do so, good cause under the APA, or both. Other commenters held the opposite view, contending that there was neither statutory authority to issue the rules on an interim final basis, nor good cause under the APA to make the rules immediately effective.

The Departments continue to believe authority existed to issue the Moral IFC as interim final rules. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of that Act, and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. The Religious and Moral IFCs fall under those statutory authorizations for the use of interim final rulemaking. Prior to the Moral IFC, the Departments issued three interim final regulations implementing this section of the PHS Act because of the needs of covered entities for immediate guidance and the weighty matters implicated by the HRSA Guidelines, including issuance of new or revised exemptions or accommodations. (75 FR 41726; 76 FR 46621; 79 FR 51092). The Departments also had good cause to issue the Moral IFC as interim final rules, for the reasons discussed therein.

In any event, the objections of some commenters to the issuance of the Moral IFC as interim final rules with request for comments does not prevent the issuance of these final rules. These final rules were issued after receiving and thoroughly considering public comments as requested in the Moral IFC. These final rules therefore comply with the APA's notice and comment requirements.

7. Health Effects of Contraception and Pregnancy

The Departments received numerous comments on the health effects of contraception and pregnancy. As noted above, some commenters supported the expanded exemptions, and others urged that contraceptives be removed from the Guidelines entirely, based on the view that pregnancy and the unborn children resulting from conception are not diseases or unhealthy conditions that are properly the subject of preventive care coverage. Such commenters further contended that hormonal contraceptives may present health risks to women. For example, they contended that studies show certain contraceptives cause, or are associated with, an increased risk of depression,[32] venous thromboembolic disease,[33] fatal pulmonary embolism,[34] thrombotic stroke and myocardial infarction (particularly among women who smoke, are hypertensive, or are older),[35] hypertension,[36] HIV–1 acquisition and transmission,[37] and breast, cervical, and liver cancers.[38] Some commenters also stated that fertility awareness based methods of birth spacing are free of similar health risks since they do not involve ingestion of chemicals. Some commenters contended that it is not the case that contraceptive access reduces unintended pregnancies or abortions.

Other commenters disagreed, citing a variety of studies they contend show health benefits caused by, or associated

[32] Commenters cited Charlotte Wessel Skovlund, et al., "Association of Hormonal Contraception with Depression," *JAMA Psychiatry* 1154, 1154 (published online Sept. 28, 2016) ("Use of hormonal contraception, especially among adolescents, was associated with subsequent use of antidepressants and a first diagnosis of depression, suggesting depression as a potential adverse effect of hormonal contraceptive use.").

[33] Commenters cited the Practice Committee of the American Society for Reproductive Medicine, "Hormonal Contraception: Recent Advances and Controversies," 82 *Fertility and Sterility* S26, S30 (2004); V.A. Van Hylckama et al., "The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study," 339 *Brit. Med. J.* b2921 (2009); Y. Vinogradova et al., "Use of Combined Oral Contraceptives and Risk of Venous Thromboembolism: Nested Case-Control Studies Using the QResearch and CPRD Databases," 350 *Brit. Med. J.* h2135 (2015) ("Current exposure to any combined oral contraceptive was associated with an increased risk of venous thromboembolism . . . compared with no exposure in the previous year."); Ø. Lidegaard et al., "Hormonal contraception and risk of venous thromboembolism: national follow-up study," 339 *Brit. Med. J.* b2890 (2009); M. de Bastos et al., "Combined oral contraceptives: venous thrombosis," Cochrane Database Syst. Rev., Mar. 3, 2014. doi: 10.1002/14651858.CD010813.pub2, available at *https://www.ncbi.nlm.nih.gov/pubmed?term=24590565;* L.J. Havrilesky et al., "Oral Contraceptive User for the Primary Prevention of Ovarian Cancer," Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* and Robert A. Hatcher et al., *Contraceptive Technology*, 405–07 (Ardent Media 18th rev. ed. 2004).

[34] Commenters cited N.R. Poulter, "Risk of Fatal Pulmonary Embolism with Oral Contraceptives," 355 *Lancet* 2088 (2000).

[35] Commenters cited Ø. Lidegaard et al., "Thrombotic Stroke and Myocardial Infarction with Hormonal Contraception, 366 *N. Engl. J. Med.* 2257, 2257 (2012) (risks "increased by a factor of 0.9 to 1.7 with oral contraceptives that included ethinyl estradiol at a dose of 20 μg and by a factor of 1.3 to 2.3 with those that included ethinyl estradiol at a dose of 30 to 40 μg"); Practice Committee of the American Society for Reproductive Medicine, "Hormonal Contraception"; M. Vessey et al., "Mortality in Relation to Oral Contraceptive Use and Cigarette Smoking," 362 *Lancet* 185, 185–91 (2003); WHO Collaborative Study of Cardiovascular Disease and Steroid Hormone Contraception, "Acute Myocardial Infarction and Combined Oral Contraceptives: Results of an International Multicentre Case-Control Study," 349 *Lancet* 1202, 1202–09 (1997); K.M. Curtis et al., "Combined Oral Contraceptive Use Among Women With Hypertension: A Systematic Review," 73 Contraception 179, 179–188 (2006); L.A. Gillum et al., "Ischemic stroke risk with oral contraceptives: A meta analysis," 284 *JAMA* 72, 72–78 (2000), available at *https://www.ncbi.nlm.nih.gov/pubmed/10872016;* and Robert A. Hatcher et al., *Contraceptive Technology*, 404–05, 445 (Ardent Media 18th rev. ed. 2004).

[36] Commenters cited Robert A. Hatcher et al., *Contraceptive Technology*, 407, 445 (Ardent Media 18th rev. ed. 2004).

[37] Commenters cited Renee Heffron et al., "Use of Hormonal Contraceptives and Risk of HIV–1 Transmission: A Prospective Cohort Study," 12 *Lancet Infectious Diseases* 19, 24 (2012) ("Use of hormonal contraceptives was associated with a two-times increase in the risk of HIV–1 acquisition by women and HIV–1 transmission from women to men."); and "Hormonal Contraception Doubles HIV Risk, Study Suggests," *Science Daily* (Oct. 4, 2011). *https://www.sciencedaily.com/releases/2011/10/111003195253.htm.*

[38] Commenters cited "Oral Contraceptives and Cancer Risk," National Cancer Institute (Mar. 21, 2012). *https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/oral-contraceptives-fact-sheet;* L.J Havrilesky et al., "Oral Contraceptive User for the Primary Prevention of Ovarian Cancer," Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html;* S. N. Bhupathiraju et al., "Exogenous hormone use: Oral contraceptives, postmenopausal hormone therapy, and health outcomes in the Nurses' Health Study," 106 *Am. J. Pub. Health* 1631, 1631–37 (2016); The World Health Organization Department of Reproductive Health and Research, "Carcinogenicity of Combined Hormonal Contraceptives and Combined Menopausal Treatment," (Sept. 2005), available at *http://www.who.int/reproductivehealth/topics/ageing/cocs_hrt_statement.pdf;* and the American Cancer Society, "Known and Probably Human Carcinogens," American Cancer Society (rev. Nov. 3, 2016), *https://www.cancer.org/cancer/cancer-causes/general-info/known-and-probable-human-carcinogens.html.*

with, contraceptive use or the prevention of unintended pregnancy. Commenters cited, for example, the 2011 Report of the Institute of Medicine (IOM), "Clinical Preventive Services for Women: Closing the Gaps," in its discussion of the negative effects associated with unintended pregnancies, as well as other studies. Such commenters contended that, by reducing unintended pregnancy, contraceptives reduce the risk of unaddressed health complications, low birth weight, preterm birth, infant mortality, and maternal mortality. Commenters also stated that studies show contraceptives are associated with a reduced risk of conditions such as ovarian cancer, colorectal cancer, and endometrial cancer, and that contraceptives treat such conditions as endometriosis, polycystic ovarian syndrome, migraines, pre-menstrual pain, menstrual regulation, and pelvic inflammatory disease.[39] Some commenters stated that pregnancy presents various health risks, such as blood clots, bleeding, anemia, high blood pressure, gestational diabetes, and death. Some commenters also contended that increased access to contraception reduces abortions.

Some commenters stated that, in the Moral IFC, the Departments relied on incorrect statements concerning scientific studies. For example, some commenters stated that there is no proven increased risk of breast cancer or other risks among contraceptive users. They criticized the Departments for citing studies, including one previewed in the 2011 IOM Report itself (Agency for Healthcare Research and Quality, Report No. 13–E002–EF (June 2013) (cited above)), discussing an association between contraceptive use and increased risks of breast and cervical cancer, and concluding there are no net cancer-reducing benefits of contraceptive use. As described in the Religious IFC, 82 FR 47804, the 2013 Agency for Healthcare Research and Quality study, and other sources, reach conclusions with which these commenters appear to disagree. The Departments consider it appropriate to consider these studies, as well as the studies cited by commenters who disagree with those conclusions.

Some commenters further criticized the Departments for saying two studies cited by the 2011 IOM Report, which asserted an associative relationship between contraceptive use and decreases in unintended pregnancy, did not on their face establish a causal relationship between a broad coverage mandate and decreases in unintended pregnancy. In this respect, as noted in the Religious IFC,[40] the purpose for the Departments' reference to such studies was to highlight the difference between a causal relationship and an associative one, as well as the difference between saying contraceptive use has a certain effect and saying a contraceptive coverage mandate (or part of that mandate affected by certain exemptions) will necessarily have (or negate, respectively) such an effect.

Commenters disagreed about the effects of some FDA-approved contraceptives on embryos. Some commenters agreed with the quotation, in the Moral IFC, of FDA materials[41] that indicate that some items it has approved as contraceptives may prevent the implantation of an embryo after fertilization. Some of those commenters cited additional scientific sources to argue that certain approved contraceptives may prevent implantation, and that, in some cases, some contraceptive items may even dislodge an embryo shortly after implantation. Other commenters disagreed with the sources cited in the Moral IFC and cited additional studies on that issue. Some commenters further criticized the Departments for asserting in the Moral IFC that some persons believe those possible effects are "abortifacient."

This objection on this issue appears to be partially one of semantics. People disagree about whether to define "conception" or "pregnancy" to occur at fertilization, when the sperm and ovum unite, or days later at implantation, when that embryo has undergone further cellular development, travelled down the fallopian tube, and implanted in the uterine wall. This question is independent of the question of what mechanisms of action FDA-approved or cleared contraceptives may have. It is also a separate question from whether members of the public assert, or believe, that it is appropriate to consider the items "abortifacient"—that is, a kind of abortion, or a medical product that causes an abortion—because they believe abortion means to cause the demise of a post-fertilization embryo inside the mother's body. Commenters referenced scientific studies and sources on both sides of the issue of whether certain contraceptives prevent implantation. Commenters and litigants have positively stated that some of them view certain contraceptives as abortifacients, for this reason. *See also Hobby Lobby*, 134 U.S. at 2765 ("The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients.").

The Departments do not take a position on the scientific, religious, or moral debates on this issue by recognizing that some people have sincere moral objections to providing contraception coverage on this basis. The Supreme Court has already recognized that such a view can form the basis of an objection based on sincerely held religious belief under RFRA.[42] Several litigants have separately raised non-religious moral objections to contraceptive coverage based on the same basic rationale. Even though there is a plausible scientific argument against the view that certain contraceptives have mechanisms of action that may prevent implantation, there is also a plausible scientific argument in favor of it—as demonstrated, for example, by FDA's statement that some contraceptives may prevent implantation and by some scientific studies cited by commenters. The Departments believe in this context we have a sufficient rationale to offer moral exemptions with respect to this Mandate.

The Departments also received comments about their discussion, located in the Religious IFC but partly relied upon in the Moral IFC, concerning uncertainty about the effects the Mandate's expanded exemptions might have on teen sexual activity. In this respect, the Departments stated, "With respect to teens, the Santelli and Melnikas study cited by IOM 2011

[39] To the extent that contraceptives are prescribed to treat health conditions, and not for preventive purposes, the Mandate would not be applicable.

[40] 82 FR at 47803–04.

[41] FDA's guide "Birth Control" specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and "may also work . . . by preventing attachment (implantation) to the womb (uterus)" of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm*.

[42] "Although many of the required, FDA-approved methods of contraception work by preventing the fertilization of an egg, four of those methods (those specifically at issue in these cases) may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus. See Brief for HHS in No. 13–354, pp. 9–10, n. 4; FDA, Birth Control: Medicines to Help You." *Hobby Lobby*, 134 S. Ct. at 2762–63. "The Hahns have accordingly excluded from the group-health-insurance plan they offer to their employees certain contraceptive methods that they consider to be abortifacients. . . . Like the Hahns, the Greens believe that life begins at conception and that it would violate their religion to facilitate access to contraceptive drugs or devices that operate after that point." *Id.* at 2765–66.

observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship). Another study, which proposed an economic model for the decision to engage in sexual activity, stated that '[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run.' "[43] Some commenters agreed with this discussion, while other commenters disagreed. Commenters who supported the expanded exemptions cited these and similar sources suggesting that limiting the exemptions to the Mandate to those that existed prior to the Religious and Moral IFCs is not tailored towards advancing the Government's interests in reducing teen pregnancy. Instead they suggested there are means of reducing teen pregnancy that are less burdensome on conscientious objections.[44] Some commenters opposing the expanded exemptions stated that school-based health centers provide access to contraceptives, thus increasing use of contraceptives by sexually active students. They also cited studies concluding that certain decreases in teen pregnancy are attributable to increased contraceptive use.[45]

Many commenters opposing the moral exemptions misunderstood the Departments' discussion of this issue. Teens are a significant part, though not the entirety, of women the IOM identified as being most at risk of unintended pregnancy. The Departments do not take a position on the empirical question of whether contraception has caused certain reductions in teen pregnancy. Rather, the Departments note that studies suggesting various causes of teen pregnancy and unintended pregnancy in general make it difficult to establish causation between exemptions to the contraceptive Mandate, and an increase in teen pregnancies in particular, or unintended pregnancies in general. For example, a 2015 study investigating the decline in teen pregnancy since 1991 attributed it to multiple factors (including, but not limited to, reduced sexual activity, falling welfare benefit levels, and expansion of family planning services in Medicaid, with the latter accounting for less than 13 percent of the decline). It concluded that "that none of the relatively easy, policy-based explanations for the recent decline in teen childbearing in the United States hold up very well to careful empirical scrutiny."[46] One study found that, during the teen pregnancy decline between 2007 through 2012, teen sexual activity was also decreasing.[47] One study concluded that falling unemployment rates in the 1990s accounted for 85 percent of the decrease in rates of first births among 18 to 19 year-old African Americans.[48] Another study found that the representation of African-American teachers was associated with a significant reduction in the African-American teen pregnancy rate.[49] One study concluded that an "increase in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy."[50] Similarly, one study from England found that, where funding for teen pregnancy prevention was reduced, there was no evidence that the reduction led to an increase in teen pregnancies.[51] Some commenters also cited studies—which are not limited to the issue of teen pregnancy—that have found that many women who have abortions report that they were using contraceptives when they became pregnant.[52]

As the Departments stated in the Religious IFC, we do not take a position on the variety of empirical questions discussed above. Likewise, these rules do not address the substantive question of whether HRSA should include contraceptives in the women's preventive services Guidelines issued under section 2713(a)(4). Rather, reexamination of the record and review of public comments has reinforced the Departments' view that the uncertainty surrounding these weighty and important issues makes it appropriate to provide the moral exemptions and accommodation if and for as long as HRSA continues to include contraceptives in the Guidelines. The federal government has a long history, particularly in certain sensitive and multi-faceted health issues, of providing moral exemptions from governmental mandates. These final rules are consistent with that history and with the discretion Congress vested in the Departments to implement the ACA.

8. Health and Equality Effects of Contraceptive Coverage Mandates

The Departments also received comments about the health and equality effects of the Mandate more broadly. Some commenters contended that the contraceptive Mandate promoted the health and equality of women, especially low income women, and promoted female participation and

[43] Citing J.S. Santelli & A.J. Melnikas, "Teen fertility in transition: recent and historic trends in the United States," 31 *Ann. Rev. Pub. Health* 371, 375–76 (2010), and Peter Arcidiacono et al., *Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?* (2005), available at *http://public.econ.duke.edu/–psarcidi/addicted13.pdf. See also* K. Buckles & D. Hungerman, "The Incidental Fertility Effects of School Condom Distribution Programs," *Nat'l Bureau of Econ. Research* Working Paper No. 22322 (June 2016), available at *http://www.nber.org/papers/w22322* ("access to condoms in schools increases teen fertility by about 10 percent" and increased sexually transmitted infections).

[44] *See* Helen Alvaré, "No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom," 58 *Vill. L. Rev.* 379, 400–02 (2013) (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[45] *See, e.g.*, Lindberg L., Santelli J., "Understanding the Decline in Adolescent Fertility in the United States, 2007–2012," 59 *J. Adolescent Health* 577–83 (Nov. 2016), *https://doi.org/10.1016/j.jadohealth.2016.06.024; see also* Comment of The Colorado Health Foundation, submission ID CMS–2014–0115–19635, *www.regulations.gov* (discussing teen pregnancy data from Colorado).

[46] Kearney MS and Levine PB, "Investigating recent trends in the U.S. birth rate," 41 *J. Health Econ.* 15–29 (2015), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629615000041.*

[47] *See, e.g.*, K. Ethier et al., "Sexual Intercourse Among High School Students—29 States and United States Overall, 2005–2015," 66 *CDC Morb. Mortal. Wkly Report* 1393, 1393–97 (Jan. 5, 2018), available at *http://dx.doi.org/10.15585/mmwr.mm665152a1* ("Nationwide, the proportion of high school students who had ever had sexual intercourse decreased significantly overall . . . .").

[48] Colen CG, Geronimus AT, and Phipps MG, "Getting a piece of the pie? The economic boom of the 1990s and declining teen birth rates in the United States," 63 *Social Science & Med.* 1531–45 (Sept. 2006), available at *https://www.sciencedirect.com/science/article/pii/S027795360600205X.*

[49] Atkins DN and Wilkins VM, "Going Beyond Reading, Writing, and Arithmetic: The Effects of Teacher Representation on Teen Pregnancy Rates," 23 *J. Pub. Admin. Research & Theory* 771–90 (Oct. 1, 2013), available at *https://academic.oup.com/jpart/article-abstract/23/4/771/963674.*

[50] E. Collins & B. Herchbein, "The Impact of Subsidized Birth Control for College Women: Evidence from the Deficit Reduction Act," *U. Mich. Pop. Studies Ctr.* Report 11–737 (May 2011), available at *https://www.psc.isr.umich.edu/pubs/pdf/rr11-737.pdf* ("[I]ncrease in the price of the Pill on college campuses . . . did not increase the rates of unintended pregnancy or sexually transmitted infections for most women").

[51] *See* D. Paton & L. Wright, "The effect of spending cuts on teen pregnancy," 54 *J. Health Econ.* 135, 135–46 (2017), available at *https://www.sciencedirect.com/science/article/abs/pii/S0167629617304551* ("Contrary to predictions made at the time of the cuts, panel data estimates provide no evidence that areas which reduced expenditure the most have experienced relative increases in teenage pregnancy rates. Rather, expenditure cuts are associated with small reductions in teen pregnancy rates").

[52] Commenters cited, for example, Guttmacher Institute, "Fact Sheet: Induced Abortion in the United States" (Jan. 2018) ("Fifty-one percent of abortion patients in 2014 were using a contraceptive method in the month they became pregnant"), available at *https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.*

equality in the workforce. Other commenters contended there was insufficient evidence showing that the expanded exemptions would harm those interests. Some of those commenters further questioned whether there was evidence to show that broad health coverage mandates of contraception lead to increased contraceptive use, reductions in unintended pregnancies, or reductions in negative effects said to be associated with unintended pregnancies. In particular, some commenters discussed a study published and revised by the Guttmacher Institute in October 2017, concluding that "[b]etween 2008 and 2014, there were no significant changes in the overall proportion of women who used a contraceptive method both among all women and among women at risk of unintended pregnancy." [53] This timeframe includes the first two years of the contraceptive Mandate's implementation. Despite some changes in the use of various methods of contraceptives, the study concluded that, "[f]or the most part, women are changing method type within the group of most or moderately effective methods and not shifting from less effective to more effective methods." Regarding the effect of this Mandate in particular, the authors concluded that "[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA (most or moderately effective methods) during the most recent time period (2012–2014) excepting small increases in implant use." The authors observed that other "[s]tudies have produced mixed evidence regarding the relationship between the implementation of the ACA and contraceptive use patterns." In explaining some possible reasons or no clear effect on contraceptive use, the authors suggested that "existence of these safety net programs [publicly funded family planning centers and Medicaid] may have dampened any impact that the ACA could have had on contraceptive use," "cost is not the only barrier to accessing a full range of method options," and "access to affordable and/or free contraception made possible through programs such as Title X" may have led to income not being associated with the use of most contraceptive methods.[54] In addition, commenters noted that in the 29 states where contraceptive coverage mandates have been imposed statewide,[55] those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[56]

Other commenters, however, disputed the significance of these state statistics, noting that, of the 29 states with contraceptive coverage mandates, only four states have laws that match the federal requirements in scope. Some also observed that, even in states with state contraceptive coverage mandates, self-insured group health plans might escape those requirements, and some states do not mandate the contraceptives to be covered at no out-of-pocket cost to the beneficiary.

The Departments have considered these experiences as relevant to the effect the exemption in these rules might have on the Mandate more broadly. The state mandates of contraceptive coverage still apply to a very large number of plans and plan participants notwithstanding ERISA preemption, and public commenters did not point to studies showing those state mandates reduced unintended pregnancies. The federal contraceptive Mandate, likewise, applies to a broad, but not entirely comprehensive, number of employers. For example, to the extent that houses of worship and integrated auxiliaries may have self-insured to avoid state health insurance contraceptive coverage mandates or for other reasons, those groups were already exempt from the federal Mandate prior to the 2017 Religious and Moral IFCs. The exemptions as set forth in the Moral IFC and in these final rules leave the contraceptive Mandate in place for nearly all entities and plans to which the Mandate has applied. The Departments are not aware of data showing that these expanded exemptions would negate any reduction in unintended pregnancies that might result from the contraceptive Mandate here.

Some commenters took a view that appears to disagree with the assertion in the 2017 Guttmacher study, that "[t]he role that the contraceptive coverage guarantee played in impacting use of contraception at the national level remains unclear, as there was no significant increase in the use of methods that would have been covered under the ACA." These commenters instead observed that, under the Mandate, more women have coverage of contraceptives and contraception counseling and that more contraceptives are provided without co-pays than before. Still others argued that the Mandate, or other expansions of contraceptive coverage, have led women to increase their use of contraception in general, or to change from less effective, less expensive contraceptive methods to more effective, more expensive contraceptive methods. Some commenters pointed to studies cited in the 2011 IOM Report recommending contraception be included in the Guidelines and argued that certain women will go without certain health care, or contraception specifically, because of cost. They contended that a smaller percentage of women delay or forego health care overall under the ACA [57] and that, according to studies, coverage of contraceptives without cost-sharing has increased use of contraceptives in certain circumstances. Some commenters also stated that studies show that decreases in unintended pregnancies are due to broader access to contraceptives. Finally, some commenters also stated that birth control access generally has led to social and economic equality for women.

The Departments have reviewed the comments, including studies submitted by commenters either supporting or opposing these expanded exemptions. Based on that review, it is not clear that merely offering the exemption in these rules will have a significant effect on contraceptive use and health, or workplace equality, for the vast majority of women benefitting from the Mandate. There is conflicting evidence regarding whether the Mandate alone, as distinct from contraceptive access more generally, has caused increased contraceptive use, reduced unintended pregnancies, or eliminated workplace disparities, where all other women's preventive services were covered without cost sharing. Without taking a definitive position on those evidentiary issues, however, the Departments

[53] M.L. Kavanaugh et al., "Contraceptive method use in the United States: trends and characteristics between 2008, 2012 and 2014," 97 *Contraception* 14, 14–21 (2018), available at *http://www.contraceptionjournal.org/article/S0010-7824(17)30478-X/pdf.*

[54] Id.

[55] See Guttmacher Institute, "Insurance Coverage of Contraceptives" (June 11, 2018); "State Requirements for Insurance Coverage of Contraceptives," Henry J. Kaiser Family Foundation (Jan. 1, 2018). *https://www.kff.org/other/state-indicator/state-requirements-for-insurance-coverage-of-contraceptives/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.*

[56] *See* Michael J. New, "Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes," 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

[57] Citing, for example, Adelle Simmons et al., "The Affordable Care Act: Promoting Better Health for Women," Table 1, ASPE (June 14, 2016). *https://aspe.hhs.gov/system/files/pdf/205066/ACAWomenHealthIssueBrief.pdf.*

conclude that the Moral IFC and these final rules—which merely withdraw the Mandate's requirement from what appears to be a small number of newly exempt entities and plans—are not likely to have negative effects on the health or equality of women nationwide. The Departments also conclude that the expanded exemptions are an appropriate policy choice left to the agencies under the relevant statutes, and, thus, an appropriate exercise of the Departments' discretion.

Moreover, the Departments conclude that the best way to balance the various policy interests at stake in the Moral IFC and these final rules is to provide the exemptions set forth herein, even if certain effects may occur among the populations actually affected by the employment of these exemptions. These rules provide tangible conscience protections for moral convictions, and impose fewer governmental burdens on various entities and individuals, some of whom have contended for several years that denying them an exemption from the contraceptive Mandate imposes a burden on their moral convictions. The Departments view the provision of those protections to preserve conscience in this health care context as an appropriate policy option, notwithstanding the widely divergent effects that public commenters have predicted based on different studies they cited. Providing the protections for moral convictions set forth in the Moral IFC and these final rules is not inconsistent with the ACA, and brings this Mandate into better alignment with various other federal conscience protections in health care, some of which have been in place for decades.

9. Other General Comments

Some commenters expressed the view that the exemptions afforded in the Moral IFC and herein violate the RFRA rights of women who might not receive contraceptive coverage as the result of these final rules, by allowing their employers to impose their moral convictions on them by removing contraceptive coverage through use of the exemption. Still other commenters stated that employer payment of insurance premiums is part of any employee's compensation package, the benefits of which employers should not be able to limit. In the Departments' view, the expanded exemptions in these final rules do not prohibit employers from providing contraceptive coverage. Instead, they lift a government burden that was imposed on some employers to provide contraceptive coverage to their employees in violation of those employers' moral convictions. The Departments do not believe RFRA requires, or has ever required, the federal government to force employers to provide contraceptive coverage. The federal government's decision to exempt some entities from a requirement to provide no-cost-sharing services to private citizens does not constitute a federal government-imposed burden on the latter under RFRA.

Some commenters asked the Departments to discuss the interaction between these rules and state laws that either require contraceptive coverage or provide exemptions from those and other requirements. Some commenters argue that providing the exemptions in these rules would negate state contraceptive requirements or narrower state exemptions. Some commenters asked that the Departments specify that these exemptions do not apply to plans governed by state laws that require contraceptive coverage.

The Departments agree that these rules only concern the applicability of the federal contraceptive Mandate imposed pursuant to section 2713(a)(4). They do not regulate state contraceptive mandates or state exemptions. If a plan is exempt under the Moral IFC and these final rules, that exemption does not necessarily exempt the plan or other insurance issuer from state laws that may apply to it. The previous regulations, which offered exemptions for houses of worship and integrated auxiliaries, did not include regulatory language negating the exemptions in states that require contraceptive coverage, although the Departments discussed the issue to some degree in various preambles of those previous regulations. The Departments do not consider it appropriate or necessary in the regulatory text of the moral exemption rules to declare whether the federal contraceptive Mandate would still apply in states that have a state contraceptive mandate, since these rules do not purport to regulate the applicability of state contraceptive mandates.[58]

Some commenters observed that, through ERISA, some entities may avoid state laws that require contraceptive coverage by self-insuring. This is a result of the application of the preemption and savings clauses contained in ERISA to state insurance regulation. *See* 29 U.S.C. 1144(a) & (b)(1).

These final rules cannot change statutory ERISA provisions, and do not change the standards applicable to ERISA preemption. To the extent Congress has decided that ERISA preemption includes preemption of state laws requiring contraceptive coverage, that decision occurred before the ACA and was not negated by the ACA. Congress did not mandate in the ACA that any Guidelines issued under section 2713(a)(4) must include contraceptives, nor that the Guidelines must force entities with moral objections to cover contraceptives.

Finally, some commenters expressed concern that providing moral exemptions to the mandate that private parties provide contraception may lead to exemptions regarding other medications or services, like vaccines. The exemptions provided in these rules, however, do not apply beyond the contraceptive coverage requirement implemented through section 2713(a)(4). Specifically, section 2713(a)(2) of the PHS Act requires coverage of "immunizations," and these exemptions do not encompass that requirement. The fact that the Departments have exempted houses of worship and integrated auxiliaries from the contraceptive Mandate since 2011 did not lead to those entities receiving exemptions under section 2713(a)(2) concerning vaccines. In addition, hundreds of entities have sued the Departments over the implementation of section 2713(a)(4), leading to two decisions of the U.S. Supreme Court, but no similar wave of lawsuits has challenged section 2713(a)(2). The expanded exemptions in these final rules are consistent with a long history of statutes protecting moral convictions from certain health care mandates concerning issues such as sterilization, abortion and birth control.

B. Text of the Final Rules

In this section, the Departments describe the regulations from the Moral IFC, public comments in response to the specific regulatory text set forth in the IFC, the Departments' response to those comments, and, in consideration of those comments, the regulatory text as finalized in this final rule. We also note the regulatory text as it existed prior to the Religious and Moral IFCs, as appropriate. The Departments consider the exemptions finalized here to be an appropriate and permissible policy

[58] Some commenters also asked that these final rules specify that exempt entities must comply with other applicable laws concerning such things as notice to plan participants or collective bargaining agreements. These final rules relieve the application of the federal contraceptive Mandate under section 2713(a)(4) to qualified exempt entities; they do not affect the applicability of other laws. In the preamble to the companion final rules concerning religious exemptions published elsewhere in today's **Federal Register**, the Departments provide guidance applicable to notices of revocation and changes that an entity may seek to make during its plan year.

choice in light of various interests at stake and the lack of a statutory requirement for the Departments to impose the Mandate on entities and plans that qualify for these exemptions.

As noted above, various members of the public provided comments that were supportive, or critical, of the regulations overall, or of significant policies pertaining to the regulations. To the extent those comments apply to the following regulatory text, the Departments have responded to them above. This section of the preamble responds to comments that pertain more specifically to particular regulatory text.

1. Restatement of Statutory Requirements of Section 2713(a) and (a)(4) of the PHS Act (26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv))

The previous regulations restated the statutory requirements of section 2713(a) and (a)(4) of the PHS Act, at 26 CFR 54.9815–2713(a)(1) and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv). The Religious IFC modified those restatements to more closely align them with the text of section 2713(a) and (a)(4) of the PHS Act. Those sections cross-reference the other sections of the Departments' rules that provide exemptions to the contraceptive Mandate. After the Religious IFC changed those sections, the Moral IFC inserted, within those cross-references, references to the new § 147.133, which contains the text of the moral exemptions. The insertions correspond to the cross-references to the religious exemptions added by the Religious IFC. The Departments finalize these parts of the Moral IFC without change.

2. Exemption for Objecting Entities Based on Moral Convictions (45 CFR 147.133(a))

The previous regulations contained no exemption concerning moral convictions, as distinct from religious beliefs. Instead, at 45 CFR 147.131(a), they offered an exemption for houses of worship and integrated auxiliaries. In the remaining part of § 147.131, the previous regulations described the accommodation process for organizations with religious objections. The Religious IFC moved the religious exemption to a new section 45 CFR 147.132, and expanded its scope. The Moral IFC created a new section 45 CFR 147.133, providing exemptions for moral convictions similar to, but not exactly the same as, the exemptions for religious beliefs set forth in § 147.132.

The prefatory language of § 147.133(a) not only specifies that certain entities are "exempt," but also explains that the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such exempt entities. This is an acknowledgement that section 2713(a)(4) requires women's preventive services coverage only "as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." To the extent the HRSA Guidelines do not provide for, or support, the application of such coverage to certain entities or plans, the Affordable Care Act does not require the coverage. Those entities or plans are "exempt" by not being subject to the requirements in the first instance. Therefore, in describing the entities or plans as "exempt," and in referring to the "exemption" encompassing those entities or plans. the Departments also affirm the non-applicability of the Guidelines to them.

The Departments wish to make clear that the expanded exemption set forth in § 147.133(a) applies to several distinct entities involved in the provision of coverage to an objecting employer's employees. This explanation is consistent with how prior regulations have worked by means of similar language. When § 147.133(a)(1) and (a)(1)(i) specify that "[a] group health plan," "health insurance coverage provided in connection with a group health plan," and "health insurance coverage offered or arranged by an objecting organization" are exempt "to the extent" of the objections "as specified in paragraph (a)(2)," that language exempts the group health plans of the sponsors that object, and their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv) (and as referenced by the parallel provisions in 26 CFR 54.9815 through 2713(a)(1)(iv) and 29 CFR 2590.715 through 2713(a)(1)(v)), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries. However, while a plan sponsor's or arranger's objection removes penalties from that group health plan's issuer, it only does so with respect to that group health plan—it does not affect the issuer's coverage for other group health plans where the plan sponsor has no qualifying objection. More information on the effects of the objection of a health insurance issuer in § 147.133(a)(1)(iii) is included below.

The exemptions in § 147.133(a)(1) apply "to the extent" of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Some commenters stated it was unclear whether the plans of entities or individuals that morally object to some but not all contraceptives would be exempt from being required to cover just the contraceptive methods as to which there is an objection, or whether the objection to some contraceptives leads to an exemption from that plan being required to cover all contraceptives. The Departments intend that a requisite moral objection to some, but not all, contraceptives would lead to an exemption only to the extent of that objection: That is, the exemption would encompass only the items to which the relevant entity or individual objects and would not encompass contraceptive methods to which the objection does not apply. To make this clearer, in these final rules the Departments finalize the prefatory language of § 147.133(a) so that the first sentence of that paragraph states that an exemption shall be included, and the Guidelines must not provide for contraceptive coverage, "to the extent of the objections specified below." The Departments have made corresponding changes to language throughout the regulatory text, to describe the exemptions as applying "to the extent" of the objection(s).

The exemptions contained in previous regulations, at § 147.131(a), did not require an exempt entity to submit any particular self-certification or notice, either to the government or to the entity's issuer or third party administrator, in order to obtain or qualify for their exemption. Similarly, under the expanded exemptions in § 147.133, the Moral IFC did not require exempt entities to comply with a self-certification process. We finalize that approach without change. Although exempt entities do not need to file notices or certifications of their exemption, and these final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan

document identifies what benefits are provided to participants and beneficiaries under the plan; if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[59] Thus, where an exemption applies and all (or a subset of) contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover.

Some commenters supported this approach, while others did not. Those in favor suggested that self-certification forms for an exemption are not necessary, could add burdens to exempt entities beyond those imposed by the previous exemption, and could give rise to objections to the self-certification process itself. Commenters also stated that requiring an exemption form for exempt entities could cause additional operational burdens for plans that have existing processes in place to handle exemptions. Other commenters favored including a self-certification process for exempt entities. They suggested that entities might abuse the availability of an exemption or use their exempt status insincerely if no self-certification process exists, and that the Mandate might be difficult to enforce without a self-certification process.

After considering the comments, the Departments continue to believe it is appropriate to not require exempt entities to submit a self-certification or notice. The previous exemption did not require a self-certification or notice, and the Departments did not collect a list of all entities that used the exemption, although there may have been thousands of houses of worship and integrated auxiliaries covered by the previous exemption and the Departments think it likely that only a small number of entities will use the moral exemption. Adding a self-certification or notice to the exemption would impose an additional paperwork burden on exempt entities that the previous regulations did not impose, and would also involve additional public costs if those certifications or notices are to be reviewed or kept on file by the government.

The Departments are not aware of instances where the lack of a self-certification under the previous exemption led to abuses or to an inability to engage in enforcement. The Mandate is enforceable through various mechanisms in the PHS Act, the Code, and ERISA. Entities that insincerely or otherwise improperly operate as if they are exempt would do so at the risk of enforcement and accountability under such mechanisms. The Departments are not aware of sufficient reasons to believe those measures and mechanisms would fail to deter entities from improperly operating as if they are exempt. Moreover, as noted above, ERISA and other plan disclosure requirements governing group health plans require provision of a comprehensive summary of the benefits covered by the plan and disclosure of any reductions in covered services or benefits, so beneficiaries will know whether their health plan claims a contraceptive Mandate exemption and will be able to raise appropriate challenges to such claims. As a consequence, the Departments believe it is an appropriate balance of various concerns expressed by commenters for these final rules to continue to not require notices or self-certifications for using the exemption.

Some commenters asked the Departments to add language indicating that an exemption cannot be invoked in the middle of a plan year, nor should it be used to the extent inconsistent with laws that apply to, or state approval of, fully insured plans. None of the previous iterations of the exemption regulations included such provisions, and the Departments do not consider them necessary in these final rules. The exemptions in these final rules only purport to exempt plans and entities from the application of the federal contraceptive coverage requirement of the Guidelines issued under section 2713(a)(4). They do not purport to exempt entities or plans from state laws concerning contraceptive coverage, or laws governing whether an entity can make a change (of whatever kind) during a plan year. Final rules governing the accommodation likewise do not purport to obviate the need to follow otherwise applicable rules about making changes during a plan year. (In the companion rules concerning religious beliefs published elsewhere in today's **Federal Register**, the Departments discuss in more detail the accommodation and when an entity seeking to revoke it would be able to do so or to notify plan participants of the revocation.)

Commenters also asked that clauses be added to the regulatory text holding issuers harmless where exemptions are invoked by plan sponsors. As discussed above, the exemption rules already specify that where an exemption applies to a group health plan, it encompasses both the group health plan and health insurance coverage provided in connection with the group health plan, and therefore encompasses any impact on the issuer of the contraceptive coverage requirement with respect to that plan. In addition, as discussed in the companion religious final rule published elsewhere in today's **Federal Register**, the Departments have added language from the previous regulations, in § 147.131(f), to protect issuers that act in reliance on certain representations made in the accommodation process. To the extent that commenters seek language offering additional protections for other incidents that might occur in connection with the invocation of an exemption, the previous exemption regulations did not include such provisions, and the Departments do not consider them necessary in these final rules. As noted above, the expanded exemptions in these final rules simply remove or narrow the contraceptive Mandate contained in, and derived from, the Guidelines for certain plans. The previous regulations included a reliance clause in the accommodation provisions, but did not specify further details regarding the relationship between exempt entities and their issuers or third party administrators. The Departments do not believe it necessary to do so in these final rules.

Commenters disagreed about the likely effects of the moral exemptions on the health coverage market. Some commenters stated that expanding the exemptions to encompass moral convictions would not cause complications in the market, while others said that it could, due to such causes as a lack of uniformity among plans, or permitting multiple risk pools. The Departments note that the extent to which plans cover contraception under the prior regulations is already far from uniform. Congress did not require all entities to comply with section 2713 of the PHS Act (under which the Mandate was promulgated)—most notably by exempting grandfathered plans. Moreover, under the previous regulations, issuers were already able to offer plans that omit contraceptives—or only some contraceptives—to houses of worship and integrated auxiliaries, and some commenters and litigants said that issuers were doing so. These cases

[59] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b-3(d), and 29 CFR 2590.715–2715. See also 45 CFR 147.200 (requiring disclosure of the "exceptions, reductions, and limitations of the coverage," including group health plans and group & individual issuers).

where plans did not need to comply with the Mandate, and the Departments' previous accommodation process which had the effect of allowing coverage not to be provided in certain self-insured church plans, together show that the importance of a uniform health coverage system is not significantly harmed by allowing plans to omit contraception in some contexts.[60]

Concerning the prospect raised by some commenters of different risk pools between men and women, section 2713(a) of the PHS Act itself provides for some preventive services coverage that applies to both men and women, and some that would apply only to women. With respect to the latter, it does not specify what, if anything, HRSA's Guidelines for women's preventives services would cover, or if contraceptive coverage will be required. The Moral IFC and these final rules do not require issuers to offer health insurance products that satisfy morally objecting entities, they simply make it legal to do so. The Mandate has been imposed only relatively recently, and the contours of its application to objecting entities has been in continual flux, due to various rulemakings and court orders. Overall, concerns raised by some public commenters have not led the Departments to consider it likely that offering these expanded exemptions will cause any injury to the uniformity or operability of the health coverage market.

3. Exemption for Certain Plan Sponsors (45 CFR 147.133(a)(1)(i))

The exemption in § 147.133(a)(1)(i) of the Moral IFC covers a group health plan and health insurance coverage for non-governmental plan sponsors that object as specified in paragraph (a)(2), and that are either nonprofit organizations, or are for-profit entities that have no publicly traded ownership interests (defined as any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934). The Departments finalize this paragraph without change, and discuss each part of the paragraph in turn.

[60] *See also Real Alternatives*, 867 F.3d 338, 389 (3d Cir. 2017) (Jordan, J., concurring in part and dissenting in part) ("Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny." (citation and internal quotation marks omitted)).

a. Plan Sponsors in General (45 CFR 147.133(a)(1)(i) Prefatory Text)

Under the plan sponsor exemption in § 147.132(a)(1)(i), the prefatory text in that paragraph specifies that it encompasses group health plans, and health insurance coverage provided in connection with such group health plans, that are sponsored by certain kinds of entities, namely, nonprofit organizations or for-profit entities that have no publicly traded ownership interests.

Such plan sponsors, if they are otherwise nonprofit organizations or for-profit entities that have no publicly traded ownership interests, can include entities that are not employers (for example, a union, or a sponsor of a multiemployer plan), where the plan sponsor objects based on sincerely held moral convictions to coverage of contraceptives or sterilization. Plan sponsors encompassed by the exemption can also include employers, and consistent with the definition of "employer" in 29 CFR 2510.3–5, can include association health plans, where the plan sponsor is a nonprofit organization or a for-profit entity that has no publicly traded ownership interests.

Some commenters objected to extending the exemption to plan sponsors that are not single employers, arguing that they could not have the same kind of moral objection that a single employer might have. Other commenters supported the protection of any plan sponsor with the requisite moral objection. The Departments conclude that it is appropriate, where a plan sponsor of a multiemployer plan or multiple employer plan adopts a moral objection using the same procedures that such a plan sponsor might use to make other decisions, to respect that decision by providing an exemption from the Mandate.

The plans of governmental employers are not covered by the plan sponsor exemption in § 147.133(a)(1)(i), which instead limits the moral exemptions to "non-governmental plan sponsors." As noted above, the Departments sought public comment on whether to extend the exemptions to non-federal governmental plan sponsors. Some commenters suggested that the moral exemptions should include government entities because other conscience laws can include government entities, such as when they oppose offering abortions. Others disagreed, contending that governmental entities should not or cannot object based on moral convictions, or that it would be unlawful for them to do so.

The Departments are sympathetic to the arguments of commenters that favor including government entities in the exemption for moral convictions. The protections outlined in the first paragraph of the Church Amendments for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Both the Weldon and Coats-Snowe Amendments also protect state and local government entities from providing, promoting, or paying for abortions in particular ways.[61] Congress has generally not limited protections for conscience based on the nature of an entity—even in the case of governmental entities.

At the same time, the Departments do not at this time have information suggesting that an exemption for governmental entities is needed or desired. The Departments have not been sued by any governmental entities raising objections to the Mandate based on non-religious moral convictions. Although the Departments sought public comment on the issue, the Departments received no public comments identifying governmental entities that need or desire such an exemption. Rather, the Departments are aware of governmental entities that, despite not possessing their own objections to contraceptive coverage, have acted to protect their employees who have conscientious objections to receiving contraceptive coverage in their employer-provided health insurance plans. *See Wieland* v. *U.S. Dep't of Health & Human Servs.*, 196 F. Supp. 1010, 1015–16 (E.D. Mo. 2016) (quoting Mo. Rev. Stat. 191.724). The individual exemption adopted in these rules will ensure the Mandate is not an obstacle to those efforts.

Thus, in light of the balance of public comments, the Departments decline to extend the moral convictions exemption to governmental entities. As is the case with the Departments' decision not to extend the moral exemption to publicly traded for-profit entities, this decision does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions

[61] Consolidated Appropriations Act, 2018, Div. H, Sec. 507(d), 132 Stat. at 764 (protecting any "hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion); 42 U.S.C. 238n (protecting entities that object to abortion, including, but not limited to, any "postgraduate physician training program").

without categorically excluding governmental entities. The Departments remain open to the possibility of future rulemaking on this issue if the Departments become aware of a governmental entity seeking to be exempt from the contraceptive Mandate.

b. Nonprofit Organizations (45 CFR 147.133(a)(1)(i)(A))

As discussed above, some commenters opposed offering exemptions based on moral convictions to any plan sponsors, and/or objected to doing so for nonprofit organizations, on various grounds, including but not limited to arguments that the benefits of contraception access should override moral objections, entities cannot assert moral objections, and moral objections burden third parties. Other commenters supported the exemptions, generally defending the interest of nonprofit organizations not to be forced to violate their moral convictions, supporting the history of government protection of moral convictions in similar contexts, and disputing the claims of opponents of the exemptions.

The Departments are aware, through litigation, of only two non-religious nonprofit organizations with moral objections to the contraceptive Mandate. Many more nonprofit religious organizations have sued suggesting—as discussed below—that the effect of this exemption for non-religious nonprofit objections to the Mandate will be far less significant than commenters who oppose the exemption believe it will. The two non-religious nonprofit organizations that challenged the Mandate in court provide a good illustration of the reasons why the Department has decided to provide this exemption to nonprofit organizations. Both organizations have said in court they oppose certain contraceptives on non-religious moral grounds as being abortifacient and state that they only hire employees who share that view. Public comments and litigation reflect that many nonprofit organizations publicly describe their beliefs and convictions. Government records and many of those groups' websites also often reflect those groups' religious or moral character, as the case may be. If a person who desires contraceptive coverage works at a nonprofit organization, the Departments view it as sufficiently likely that the person would know, or would know to ask, whether the organization offers such coverage. The Departments are not aware of federal laws that would require a nonprofit organization that opposes contraceptive coverage to hire a person who disagrees with the organization's view on contraceptive coverage. Instead, nonprofit organizations generally have access to a First Amendment right of expressive association to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[62]

The Departments agree with commenters who support offering the exemption to nonprofit organizations and believe that doing so is an appropriate protection and is not likely to have a significant impact on women who want contraceptive coverage.

c. For-Profit Entities (45 CFR 147.133(a)(1)(i)(B))

With respect to for-profit organizations addressed in § 147.133(a)(1)(i)(B), in the Moral IFC, the Departments did not limit the exemption to nonprofit organizations, but also included some for-profit entities. Some commenters supported including for-profit entities in the exemption, saying owners of such entities exercise their moral convictions through their businesses, and that such owners should not be burdened by a federal governmental contraceptive Mandate. Other commenters opposed extending the exemption to closely held for-profit entities, saying the entities cannot exercise moral convictions or should not have their moral opposition to contraceptive coverage protected by the exemption. Some commenters stated that the entities should not be able to impose their beliefs about contraceptive coverage on their employees and that doing so constitutes discrimination.

The Departments agree with commenters who support including some for-profit entities in the exemption. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities, without regard to whether they operate as nonprofit organizations or for-profit entities. In addition, nearly half of the states either impose no contraceptive coverage requirement or offer "an almost unlimited" exemption encompassing both "religious and secular organizations."[63] States also generally protect moral convictions in other health care conscience laws whether or not an entity operates as a nonprofit.[64]

Extending the exemption to certain for-profit entities is also consistent with the Supreme Court's ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, the pursuit of religious beliefs), regardless of whether the entity operates as a nonprofit organization and rejected the Departments' argument to the contrary. 134 S. Ct. at 2768–75. The mechanisms by which a for-profit company makes decisions of conscience, or resolves disputes on those issues among their owners, are problems that "state corporate law provides a ready means" of solving. *Id.* at 2774–75. Some reports and industry experts have indicated that few for-profit entities beyond those that had originally challenged the Mandate have sought relief from it after *Hobby Lobby*.[65] Because all of those appear to be informed by religious beliefs, extending the exemption to entities with non-religious moral convictions would seem to have an even smaller impact on access to contraceptive coverage.

The Moral IFC only extended the exemption covering for-profit entities to those that are closely held, not to for-profit entities that are publicly traded, but asked for comment on whether publicly traded entities should be included in the moral exemption. In this way the Moral IFC differed from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in the Religious IFC, at § 147.132(a)(1), finalized in companion rules published elsewhere in today's **Federal Register**.

Some commenters supported including publicly traded entities in the moral exemption, contending that publicly traded entities have historically taken various positions on important public concerns beyond merely seeking the company's own profits, and that nothing in principle would preclude them from using the same mechanisms of corporate decision-making to establish and exercise moral convictions against contraceptive coverage. They observed that large publicly traded entities are exempt from the contraceptive Mandate by means of the grandfathering provision of the ACA, so

[62] Notably, "the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.'" *Boy Scouts of America* v. *Dale*, 530 U.S. 640, 655 (2000).

[63] "Insurance Coverage of Contraceptives," The Guttmacher Institute (June 11, 2018), *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives*.

[64] *See, e.g.*, "Refusing to Provide Health Services," The Guttmacher Institute (June 1, 2018), *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services*.

[65] See Jennifer Haberkorn, "Two years later, few Hobby Lobby copycats emerge," *Politico* (Oct. 11, 2016), *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627*.

that it is inappropriate to refuse to exempt publicly traded entities that actually have sincerely held moral convictions against compliance with the Mandate. They further argued that in some instances there are closely held companies that are as large as publicly traded companies of significant size. They also stated that other protections for moral convictions in certain federal health care conscience statutes do not preclude the application of such protections to certain entities on the basis that they are not closely held, and federal law defines "persons" to include all forms of corporations, not just closely held corporations, at 1 U.S.C. 1. Additionally, some commenters were concerned that not providing a moral exemption for publicly traded for-profit entities but allowing a religious exemption for publicly traded for-profit entities (as was allowed in the Religious IFC, and as is allowed in the companion religious final rules published elsewhere in today's **Federal Register**), may raise Establishment Clause questions, may cause confusion to the public, and may make the exemptions more difficult for the Departments and enforcing agencies to administer. They stated that it is incongruous to include publicly traded entities in the exemption for religious beliefs, but exclude them from the exemption for moral convictions.

Other commenters opposed including publicly traded companies in these moral exemptions. Some stated that such companies could not exercise moral convictions and opposed the effects on women if they would. They also objected that including such companies, along with closely held businesses, would extend the exemptions to all or virtually all companies. Some commenters stated that many publicly traded companies would use a moral exemption if available to them, because many closely held for-profit businesses expressed religious objections to the Mandate, or availed themselves of the religious accommodation.

As is the case for non-federal governmental employers, the Departments are sympathetic to the arguments of commenters that favor including publicly traded entities in the exemption for moral convictions. In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without regard to their ownership status. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations; the protections of the Church Amendments do not turn on the nature of the entity, whether public, private, nonprofit, for-profit, or governmental. (42 U.S.C. 300a–7(b)). Thus, under section 300a–7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a–7(b), the protections of that section would apply. Other federal conscience protections in the health sector apply in the same manner:

- The Coats-Snowe Amendment (42 U.S.C. 238n) provides certain protections for health care entities and postgraduate physician training programs that, among other things, choose not to perform, refer for, or provide training for, abortions.
- The Weldon Amendment [66] provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans that do not provide, pay for, provide coverage of, or refer for abortions.
- The ACA provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing. (42 U.S.C. 18113).[67]
- Social Security Act sections 1852(j)(3)(B) (Medicare) and 1932(b)(3)(B) (Medicaid), 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3)(B), provide protections so that the statutes cannot be construed to require organizations that offer Medicare Advantage and Medicaid managed care plans in certain contexts to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds.
- Congress's most recent statement on contraceptive coverage specified that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act, 2018, Public Law 115–141, Div. E, Sec. 808.

In all of these instances, Congress did not limit the protection for conscience based on the nature of the entity—and did not exclude publicly traded entities from protection.

At the same time, as stated in the Moral IFC, the Departments continue to lack significant information about whether there is a need to extend the expanded exemption to publicly traded entities. The Departments have been sued by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, as well as by closely held for-profit entities expressing religious objections, but not by any publicly traded entities. In addition, the Departments sought public comments on whether publicly traded entities might benefit from extending the moral exemption to them. No such entities were brought to the attention of the Department through the comment process. The Supreme Court concluded it is improbable that publicly traded companies with numerous "unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs." *Hobby Lobby*, 134 S. Ct. at 2774. It would appear to be even less probable that publicly traded entities would adopt that view based on non-religious moral convictions.

In light of the balance of public comments, the Departments decline to extend the moral convictions exemption to publicly traded entities. Because the Departments are aware of so many closely-held for-profit entities with religious objections to contraceptive coverage, and of some nonprofit entities with non-religious moral objections to contraceptive coverage, the Departments believe it is reasonably possible that closely held for-profit entities with non-religious moral objections to contraceptive coverage might exist or come into being. The Departments have also concluded that it is reasonably possible, even if improbable, that publicly traded entities with religious objections to contraceptive coverage might exist or come into being. But the Departments conclude there is not a similar probability that publicly traded for-profit entities with non-religious moral objections to contraceptive

[66] See Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d) (Mar. 2018).

[67] The lack of the limitation in this provision may be particularly relevant since it was enacted in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—were promulgated.

coverage may exist and need to be included in these expanded exemptions. The decision to not extend the moral exemption to publicly traded for-profit entities in these rules does not reflect a disagreement with the various conscience statutes that provide exemptions for moral convictions without categorically excluding publicly traded entities. The Departments remain open to the possibility of future rulemaking on this issue, if we become aware of the need to expand the exemptions to publicly traded corporations with non-religious moral objections to all (or a subset of) contraceptives.

In contrast, the Departments finalize, without change, the Moral IFC's extension of the exemptions in these rules to closely held for-profit entities with moral convictions opposed to offering coverage of some or all contraceptives. The Departments conclude that it is sufficiently likely that closely held for-profit entities exist or may come into being and may maintain moral objections to certain contraceptives, so as to support including them in these expanded exemptions. The Departments seek to remove an obstacle that might prevent individuals with moral objections from forming or maintaining such small or closely held businesses and providing health coverage to their employees in accordance with their moral convictions.

In defining what constitutes a closely held for-profit entity to which these exemptions extend, the Moral IFC used language derived from the July 2015 final regulations. Those regulations, in offering the accommodation (not an exemption) to religious (not moral) closely held for-profit entities, did so by attempting to positively define what constitutes a closely held entity, formulating a multi-factor, and partially open-ended, definition for that purpose. (80 FR 41313). Any such positive definition runs up against the myriad state differences in defining such entities and potentially intrudes into a traditional area of state regulation of business organizations. Instead of attempting to positively define closely held businesses in the Moral IFC, however, the Departments considered it much clearer, effective, and preferable to define the category negatively, by reference to one element of the previous definition: that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

4. Institutions of Higher Education (45 CFR 147.133(a)(1)(ii))

The previous regulations did not exempt plans arranged by institutions of higher education, although they did include, in the accommodation, plans arranged by institutions of higher education similarly to the way in which the regulations provided the accommodation to plans of nonprofit religious employers. (See 80 FR 41347). The Moral IFC provided an exemption, in § 147.133(a)(1)(ii), encompassing institutions of higher education that arrange student health insurance coverage, and stating the exemption would operate in a manner comparable to the exemption for employers with respect to plans they sponsor. In these final rules, the Departments finalize § 147.133(a)(1)(ii) with one change.

These rules treat the health plans of institutions of higher education that arrange student health insurance coverage similarly to the way in which the rules treat the plans of employers. The rules do so by making such student health plans eligible for the expanded exemptions, and by permitting them the option of electing to utilize the accommodation process. Thus, these rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002) with objections to the Mandate based on sincerely held moral convictions, to their arrangement of student health insurance coverage, in a manner comparable to the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

Some commenters supported including, in the exemptions, institutions of higher education that provide health coverage for students through student health plans but have moral objections to providing certain contraceptive coverage. They stated that moral exemptions allow freedom for certain institutions of higher education to exist, and this in turn gives students the choice of institutions that hold different views on important issues such as contraceptives and abortifacients. Other commenters opposed including the exemption, asserting that expanding the exemption would negatively impact female students because institutions of higher education might not cover contraceptives in student health plans, women enrolled in those plans would not receive access to birth control, and an increased number of unintended pregnancies would result.

In the Departments' view, the reasons for extending the exemption to institutions of higher education are similar to the reasons, discussed above, for extending the exemption to other nonprofit organizations. The Departments are not aware of any institutions of higher education that arrange student health insurance coverage and object to the Mandate based on non-religious moral convictions. But because the Departments have been sued by several institutions of higher education that arrange student health insurance coverage and object to the Mandate based on religious beliefs and by several nonprofit organizations with moral objections, the Departments believe the existence of institutions of higher education with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible to justify including protections for such entities in these final rules.

The Departments conclude that this aspect of the exemption is likely to have a minimal impact on contraceptive coverage for women at institutions of higher education. As noted above, the Departments are not aware of any institutions of higher education that would currently qualify for the objection. In addition, only a minority of students in higher education receive health insurance coverage from plans arranged by their colleges or universities, as opposed to from other sources, and an even smaller number receive such coverage from schools objecting to contraceptive coverage. Exempting institutions of higher education that object to contraceptive coverage based on moral convictions does not affect student health insurance contraceptive coverage at the vast majority of institutions of higher education. The exemption simply makes it legal under federal law for institutions to adhere to moral convictions that oppose contraception, without facing penalties for non-compliance that could threaten their existence. This removes a possible barrier to diversity in the nation's higher education system, because it makes it easier for students to attend institutions of higher education that hold those views, if the institutions exist or come into being and students choose to attend them. Moreover, because institutions of higher education have no legal obligation to sponsor student health insurance coverage, providing this moral exemption removes an obstacle to such institutions sponsoring student health insurance coverage, thus possibly encouraging

more widespread health insurance coverage.

As noted above, after seeking public comment on whether the final moral exemptions rules should be extended to include non-federal governmental entities, the Departments have concluded they should only include non-governmental entities. For the same reasons, the Departments are inserting a reference into § 147.133(a)(1)(ii) specifying that it includes an institution of higher education ''which is non-governmental.'' This language is parallel to the same limiting phrase used in the religious exemptions rule governing institutions of higher education, at § 147.132(a)(1)(ii). Thus, the first sentence of § 147.133(a)(1)(ii) is finalized to read: ''An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section.'' The remaining text of § 147.133(a)(1)(ii) is finalized without change.

5. Health Insurance Issuers (45 CFR 147.133(a)(1)(iii))

The Moral IFC extended the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services. The issuer exemption only applied to the group health plan if the plan itself was also exempt under an exemption for the plan sponsor or individuals. In these final rules, the Departments finalize § 147.133(a)(1)(iii) without change.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing contraceptive coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors—or in the case of individual insurance coverage, individuals—who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services, are plan sponsors or individuals who themselves object and whose plans are otherwise exempt based on that objection. An exempt issuer can then offer an exempt product to an entity or individual that is exempt based on either the moral exemptions for entities and individuals, or the religious exemptions for entities and individuals. Thus, the issuer exemption specifies that, where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv), unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer under this paragraph (a)(1)(iii) that does not include some or all contraceptive services, are plan sponsors or individuals who themselves object and are exempt.

Under these rules, issuers that hold their own objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on their moral convictions, or if they are exempt based on their religious beliefs under the companion final rules published elsewhere in today's **Federal Register**. Likewise, issuers with sincerely held religious beliefs, that are exempt under those companion final rules, could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Some commenters supported including this exemption for issuers in these rules, both to protect the moral convictions of issuers, and so that, in the future, issuers would be free to organize that may wish to specifically serve plan sponsors and individuals that object to contraception based on religious or moral reasons. Other commenters objected to including an exemption for issuers. Some commenters stated that issuers cannot exercise moral convictions, while others stated that exempting issuers would threaten contraceptive coverage for women. Some commenters stated that it was arbitrary and capricious for the Departments to provide an exemption for issuers if they do not know that issuers with qualifying moral objections exist.

The Departments consider it appropriate to provide this exemption for issuers. Because the issuer exemption only applies where an independently exempt policyholder (entity or individual) is involved, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual or group insurance coverage.

The issuer exemption serves several interests, even though the Departments are not currently aware of existing issuers that would use it. As noted by some commenters, allowing issuers to be exempt, at least with respect to plan sponsors, plans, and individuals that independently qualify for an exemption, will remove a possible obstacle to issuers with moral convictions being organized in the future to serve entities and individuals that want plans that respect their religious beliefs or moral convictions. Furthermore, permitting issuers to object to offering contraceptive coverage based on sincerely held moral convictions will allow issuers to continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4), or related provisions, for their failure to provide contraceptive coverage. In this way, the issuer exemption serves to protect objecting issuers both from being required to issue policies that cover contraception in violation of the issuers' sincerely held moral convictions and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines.

The Departments reject the proposition that issuers cannot exercise moral convictions. Many federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicare Advantage or Medicaid. The Weldon Amendment specifically protects, among other entities, HMOs, health insurance plans, and ''any other kind of health care facility[ies], organization[s] or plan[s]'' as a ''health care entity'' from being required to provide coverage of, or pay for, abortions. See, for example, Consolidated Appropriations Act, 2018, Public Law 115–141, Div. H, Sec. 507(d).[68] The most recently enacted Consolidated Appropriations Act declares that Congress supports a

[68] ACA section 1553 protects an identically defined group of ''health care entities,'' including provider-sponsored organizations, HMOs, health insurance plans, and ''any other kind of . . . plan,'' from being subject to discrimination on the basis that it does not provide any health care item or service furnishing for the purpose of assisted suicide, euthanasia, mercy killing, and the like. ACA section 1553, 42 U.S.C. 18113.

"conscience clause" to protect moral convictions concerning "the provision of contraceptive coverage by health insurance plans." *See id.* at Div. E, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion Religious IFC and final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**.[69]

6. Description of the Moral Objection (45 CFR 147.133(a)(2))

The Moral IFC set forth the scope of the moral objection of objecting entities in § 147.133(a)(2), so that it applies to the extent an entity described in paragraph (a)(1), based on sincerely held moral convictions, objects to "establishing, maintaining, providing, offering, or arranging" either "coverage or payments" for contraceptives, or "for a plan, issuer, or third party administrator that provides or arranges such coverage or payments." The Departments are finalizing this exemption with structural changes separating the second half of the sentence into separate subparagraphs, so as to more clearly specify, as set forth in the Moral IFC text, that the objection may pertain either to coverage or payments for contraceptives, or to a plan, issuer, or third party administrator that provides or arranges such coverage or payments.

Some commenters observed that, by allowing exempt plan sponsors to object to "some or all" contraceptives, this might yield a cafeteria-style approach where different plan sponsors choose various combinations of contraceptives that they wish to cover. Some commenters further observed that this might create a burden on issuers or third party administrators.

The Departments have concluded, however, that just as the previous exemption rules allowed certain religious plan sponsors to object to some or all contraceptives, it is appropriate to maintain that flexibility for entities covered by the expanded exemption. These rules do not require any issuer or third party administrator to contract with an exempt entity or individual if the issuer or third party administrator does not wish to do so, including because the issuer or third party administrator does not wish to offer an unusual plan variation. These rules simply remove the federal Mandate, in some cases, where it could have led to penalties on an employer, issuer, or third party administrator if they wished to sponsor, provide, or administer a plan that omits contraceptive coverage in the presence of a qualifying moral objection. That approach is consistent with the approach under the previous regulations, which did not require issuers and third party administrators to contract with exempt plans of houses of worship or integrated auxiliaries if they did not wish to do so.

The definition does not specify that the moral convictions that can support an exemption need to be non-religious moral convictions. We find it unnecessary to limit the definition in that way. Even though moral convictions need not be based on religious beliefs, religious beliefs can have a moral component. It is not always clear whether a moral conviction is based on religious tenets. As noted in *Welsh*, a moral conviction can be "purely ethical or moral in source and content but that nevertheless . . . occupy in the life of that individual a place parallel to that filled by God [and] function as a religion in his life." 398 U.S at 340. One reason for providing exemptions for moral convictions is so that the government need not engage in the potentially difficult task of parsing which convictions are religious and which are not. If sincerely held moral convictions supporting an exemption are religious, they will be encompassed by the exemption for sincerely held religious beliefs. If the moral convictions are not also religious, or if their religious quality is unclear but they are ethical or moral, they can qualify as sincerely held moral convictions under these rules if the other requirements of these rules are met.

The Departments are not aware of any entities that qualify for an exemption under the religious exemptions finalized elsewhere in today's **Federal Register**, but not under the moral exemptions finalized here, such as publicly traded entities. If publicly traded entities object to the Mandate, it seems unlikely their objection is based on moral convictions and not religious beliefs, given that many more objections to the Mandate have been based on religious beliefs. Thus, the Departments find it unlikely that they would be faced with a situation where a publicly traded entity, for example, has an objection to the contraceptive Mandate, but it is not clear whether that objection is based on sincerely held religious beliefs or merely based on sincerely held moral convictions.

7. Individuals (45 CFR 147.133(b))

The previous regulations did not provide an exemption for objecting individuals. The Moral IFC provided such an exemption for objecting individuals (referred to here as the "individual exemption"), using the following language at § 147.133(b): "Objecting individuals". Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions."

The Departments finalize this language, with changes in response to public comments in some of the text and in a new sentence at the end of the paragraph that clarify how the exemption applies.

Section 147.133(b) sets forth a special rule pertaining to individuals (referred to here as the "individual exemption"). This rule exempts plans of certain individuals with moral objections to contraceptive coverage where the plan sponsor and, as applicable, issuer is willing to provide a plan compliant with the individuals' objections to such plan sponsors or individuals, as applicable.

Some commenters supported this exemption as providing appropriate protections for the moral convictions of individuals who obtain their insurance coverage in such places as the individual market or exchanges, or who obtain coverage from a group health plan sponsor that does not object to coverage of contraceptives but is willing (and, as applicable, the issuer is also willing) to provide coverage consistent with an individual's moral objections. They commented that this exemption

[69] The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for employers. Because the issuer exemption operates more narrowly than the exemption for plan sponsors operates, in the ways described here (*i.e.*, the issuer exemption does not operate unless the plan sponsor or individual, as applicable, is also exempt), and exists in part to help preserve market options for objecting plan sponsors and individuals, the Departments consider it appropriate to not draw such a distinction among issuers.

would free individuals from having their moral convictions placed in tension with their desire for health coverage. They also contended that the individual exemption would not undermine any government interests behind the contraceptive Mandate, since the individuals would be choosing not to have the coverage. Some commenters also observed that, by specifying that the individual exemption only operates where the plan sponsor and issuer, as applicable, are willing to provide coverage that is consistent with the objection, the exemption would not impose burdens on the insurance market because the possibility of such burdens would be factored into the willingness of an employer or issuer to offer such coverage.

Other commenters disagreed and contended that allowing the individual exemption would cause burden and confusion in the insurance market. Some commenters also suggested that the individual exemption should not allow the offering of a separate group health plan because doing so could cause various administrative burdens.

The Departments agree with the commenters who suggested the individual exemption will not burden the insurance market, and, therefore, conclude that it is appropriate to provide the individual exemption where a plan sponsor and, as applicable, issuer are willing to cooperate in doing so. The Departments note that this individual exemption only operates in the case where the issuer is willing to provide the separate option; in the case of coverage provided by a group health plan sponsor, where the plan sponsor is willing; or in the case where both a plan sponsor and issuer are involved, both are willing. The Departments conclude that it is appropriate to provide the individual exemption so that the Mandate will not serve as an obstacle among these various options. Practical difficulties that may be implicated by one option or another will likely be factored into whether plan sponsors and issuers are willing to offer particular options in individual cases. But the Departments do not wish to pose an obstacle to the offering of such coverage.

The Departments note that their decision is consistent with the decision by Congress to provide protections in certain contexts for individuals who object to prescribing or providing contraceptives contrary to their moral convictions. *See, for example,* Consolidated Appropriations Act of 2018, Div. E, Sec. 726(c) (Mar. 23, 2018). While some commenters argued that such express protections are narrow, Congress likewise provided that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions". *Id.* at Div. E, Sec. 808. A moral exemption for individuals would not be effective if the government did not, at the same time, permit issuers and group health plans to provide individuals with policies that comply with their moral convictions.

The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan generally, or, as applicable, to any other individual policies the issuer offers. Thus, this individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations "does not undermine the governmental interests furthered by the contraceptive coverage requirement." (78 FR 39874). For parallel reasons, as the Departments stated in the Moral IFC (83 FR at 47853 through 47854), this individual exemption does not undermine the governmental interests furthered by the contraceptive coverage requirement, because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the state is not permitted to discriminate against insurance issuers that offer group health insurance policies without coverage for contraception based on employees' religious beliefs "or moral convictions," or against the individual employees who accept such offers. *See Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption in these rules, employers sponsoring governmental plans would be free to honor the moral objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

In the separate companion IFC to the Moral IFC—the Religious IFC—the Departments, at § 147.133(b), provided a similar individual exemption, but we used slightly different operative language. Where the Moral IFC said a willing issuer and plan sponsor may offer "a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects" under the individual exemption, the Religious IFC described what may be offered to objecting individuals as "a separate benefit package option, or a separate policy, certificate or contract of insurance." Some commenters observed this difference and asked whether the language was intended to encompass the same options. The Departments intended these descriptions to include the same scope of options. Some commenters suggested that the individual exemption should not allow the offering of "a separate group health plan," because doing so could cause various administrative burdens. The Departments disagree, since group health plan sponsors and group and individual health insurance issuers would be free to decline to provide that option, including because of administrative burdens. In addition, the Departments wish to clarify that, where an employee claims the exemption, a willing issuer and a willing employer may, where otherwise permitted, offer the employee participation in a group health insurance policy or benefit option that complies with the employee's objection. Consequently, these rules finalize the individual exemption by making a technical change to the language to adopt the formulation, "a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects."

This individual exemption cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of state law that requires coverage of such contraceptives or

sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held moral objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4), and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these rules do not affect such other laws or terms.

The Departments received numerous comments about the administrative burden from the potential variations in moral convictions held by individuals. Some commenters welcomed the ability of individuals covered by the individual exemption to be able to assert an objection to either some or all contraceptives, while others expressed concern that the variations in the kinds of contraceptive coverage to which individuals object might make it difficult for willing plan sponsors and issuers to provide coverage that complies with the moral convictions of an exempt individual.

If an individual only objects to some contraceptives, and the individual's issuer and, as applicable, plan sponsor are willing to provide the individual a package of benefits omitting such coverage, but for practical reasons can only do so by providing the individual with coverage that omits all—not just some—contraceptives, the Departments believe that it favors individual freedom and market choice, and does not harm others, to allow the issuer and plan sponsor to provide, in that case, a plan omitting all contraceptives if the individual is willing to enroll in that plan. The language of the individual exemption set forth in the Moral IFC implied this conclusion by specifying that the Guidelines requirement of contraceptive coverage did not apply where the individual objected to some or all contraceptives. Notably, that language differed from the language applicable to the exemptions under § 147.133(a), which specifies that those exemptions apply "to the extent" of the moral objections, so that, as discussed above, they include only those contraceptive methods to which the objection applied. In response to comments suggesting the language of the individual exemption was not sufficiently clear on this distinction, however, the Departments in these rules finalize the individual exemption at § 147.133(b), with the following change, by adding the following sentence at the end of the paragraph: "Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services."

Some commenters asked for plain language guidance and examples about how the individual exemption might apply in the context of employer-sponsored insurance. Here is one such example. An employee is enrolled in group health coverage through her employer. The plan is fully insured. If the employee has sincerely held moral convictions objecting to her plan including coverage for contraceptives, she could raise this with her employer. If the employer is willing to offer her a plan that omits contraceptives, the employer could discuss this with the insurance agent or issuer. If the issuer is also willing to offer the employer, with respect to the employee, a group health insurance policy that omits contraceptive coverage, the individual exemption would make it legal for the group health insurance issuer to omit contraceptives for her and her beneficiaries under her policy, for her employer to sponsor that plan for her, and for the issuer to issue such a plan to the employer, to cover that employee. This would not affect other employees' plans—those plans would still be subject to the Mandate and would continue to cover contraceptives. But if either the employer, or the issuer, is not willing (for whatever reason) to offer a plan or a policy for that employee that omits contraceptive coverage, these rules do not require them to do so. The employee would have the choice of staying enrolled in a plan with its coverage of contraceptives, not enrolling in that plan, seeking coverage elsewhere, or seeking employment elsewhere.

For all these reasons, these rules adopt the individual exemption language from the Religious IFC with changes, to read as follows: "(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services."

8. Accommodation (45 CFR 147.131, 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A)

The previous regulations did not offer the accommodation process to entities with moral non-religious objections. The Religious IFC amended the accommodation regulations to offer it to all entities that are exempt on the basis of religious beliefs under § 147.132, as an optional process in which such entities could participate voluntarily. The Moral IFC did not change that accommodation process, but inserted references in it to the new section § 147.133, alongside the references to section § 147.132. These changes made entities eligible for the voluntary accommodation process if they are exempt on the basis of moral convictions. The references were inserted in 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A.

In these rules, the Departments finalize, without change, the Moral IFC's revisions of 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A. The operation of the accommodation process, changes made in the Religious IFC, and public comments concerning the accommodation, are more fully described in the Religious IFC, and in the companion final rules concerning the religious exemptions and accommodation, published elsewhere in today's **Federal Register**. Those descriptions are incorporated here by reference to the extent they apply to these rules.

Many commenters supported extending the accommodation process to entities with objections based on moral convictions. Others objected to doing so, raising arguments parallel to their objections to creating exemptions for group health plan sponsors with moral convictions. For much the same reasons discussed above concerning why the Departments find it appropriate to exempt entities with moral objections to contraceptive coverage, the Departments find it appropriate to extend the optional accommodation process to these entities. The Departments observe that, to the extent such entities wish to use the process, it will not be an obstacle to contraceptive coverage, but will instead help deliver contraceptive coverage to women who receive health coverage from such entities while respecting the moral convictions of the entities. The Departments are not aware of entities with non-religious moral convictions against contraceptive coverage that also consider the accommodation acceptable and would opt into it, but we are aware of a small number of entities with non-religious moral objections to the Mandate. The Departments, therefore, continue to consider it appropriate to extend the optional accommodation to such entities in case any wish to use it. Below, albeit based on very limited data, the Departments estimate that a small number of entities with non-religious moral objections may use the accommodation process.

9. Definition of Contraceptives for the Purpose of These Final Rules

The previous regulations did not define contraceptive services. The Guidelines issued in 2011 included, under "Contraceptive methods and counseling," "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." The previous regulations concerning the exemption and the accommodation used the terms "contraceptive services" and "contraceptive coverage" as catch-all terms to encompass all of those Guidelines requirements. The 2016 update to the Guidelines are similarly worded. Under "Contraception," they include the "full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration," "instruction in fertility awareness-based methods," and "[c]ontraceptive care" to "include contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.*, management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method)." [70]

To more explicitly state that the expanded exemptions encompass any of the contraceptive or sterilization services, items, procedures, or related patient education or information that have been required under the Guidelines, the Moral IFC included a definition of contraceptive services, benefits or coverage, at 45 CFR 147.133(c). These rules finalize that definition without change.

10. Severability

The Departments finalize, without change, the severability clause set forth at § 147.133(d).

C. Other Public Comments

1. Items Approved as Contraceptives But Used To Treat Existing Conditions

Some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions, and that women use them for non-contraceptive purposes. Certain commenters urged the Departments to clarify that the final rules do not permit employers to exclude from coverage medically necessary prescription drugs used for non-preventive services. Some commenters suggested that moral objections to the Mandate should not be permitted in cases where contraceptive methods are used to treat such existing medical conditions and not for preventive purposes, even if those contraceptive methods can also be used for contraceptive purposes.

Section 2713(a)(4) only applies to "preventive" care and screenings. The statute does not allow the Guidelines to mandate coverage of services provided solely for a non-preventive use, such as the treatment of an existing condition. The Guidelines implementing this section of the statute are consistent with that narrow authority. They state repeatedly that they apply to "preventive" services or care.[71] The requirement in the Guidelines concerning "contraception" specifies several times that it encompasses "contraceptives," that is, medical products, methods, and services applied for "contraceptive" uses. The Guidelines do not require coverage of care and screenings that are non-preventive, and the contraception portion of those Guidelines do not require coverage of medical products, methods, care, and screenings that are non-contraceptive in purpose or use. The Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that FDA has approved for contraceptive use is prescribed in whole or in part for such purpose or intended use. Section 2713(a)(4) does not authorize the Departments to require coverage of drugs prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[72] The extent to which contraceptives are covered to treat non-preventive conditions would be determined by application of the requirement section 1302(b)(1)(F) of the ACA to cover prescription drugs (where applicable), implementing regulations at 45 CFR 156.122, and 156.125, and plans' decisions about the basket of medicines to cover for these conditions.

Some commenters observed that pharmacy claims do not include a medical diagnosis code, so that plans may be unable to discern whether a drug approved by FDA for contraceptive uses is actually applied for a preventive or contraceptive use. Section 2713(a)(4), however, draws a distinction between preventive and other kinds of care and screenings. That subsection does not authorize the Departments to impose a coverage mandate of services that are not at least partly applied for a preventive use, and the Guidelines themselves do not require coverage of care unless it is contraceptive in purpose. These rules do not prohibit issuers from covering drugs and devices that are approved for contraceptive uses even when those drugs and devices are

[70] "Women's Preventive Services Guidelines," HRSA (last reviewed Oct. 2017), *https://www.hrsa.gov/womens-guidelines-2016/index.html.*

[71] *Id.*

[72] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that "there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy." 77 FR 8727 & n.7. This was not, however, an assertion that section 2713(a)(4) or the Guidelines require coverage of "contraceptive" methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead, it was an observation that such drugs—generally referred to as "contraceptives"—also have some alternate beneficial uses to treat existing conditions. For the purposes of these final rules, the Departments clarify here that the previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines and the contraceptive Mandate.

prescribed for non-preventive, non-contraceptive purposes. As discussed above, these final rules do not purport to delineate the items HRSA will include in the Guidelines, but only concern expanded exemptions and accommodations that apply if the Guidelines require contraceptive coverage. Therefore, the Departments do not consider it appropriate to specify in these final rules that, under section 2713(a)(4), exempt organizations must provide coverage for drugs or items prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.

2. Comments Concerning Regulatory Impact

Some commenters agreed with the Departments' statement in the Moral IFC that the moral exemptions are likely to affect only a very small number of women otherwise receiving coverage under the Mandate. Other commenters disagreed, stating that the exemptions could take contraceptive coverage away from many or most women. Still others opposed establishing the exemptions, but contended that accurately determining the number of women affected by the exemptions is not possible. Public comments included various statements that these exemptions would impact coverage for a large number of women, while others stated they would affect only a very small number. But few, if any, public commenters provided data predicting a precise number of entities that would make use of the exemptions for moral convictions nor a precise number of employees that would potentially be affected.

After reviewing the public comments, the Departments do not find the suggestions of commenters who predicted a very large impact any more reliable than the estimates set forth in the Religious and Moral IFCs. Therefore, the Departments conclude that the estimates of regulatory impact made in the Religious and Moral IFCs are still the best estimates available. The Departments' estimates are discussed in more detail in the following section.

III. Economic Impact and Paperwork Burden

The Departments have examined the impacts of these final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and an "economically significant" regulatory action is subject to review by OMB. As discussed below regarding their anticipated effects, the these final rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of "economically significant" under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final rules and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

The Religious IFC amended the Departments' July 2015 final regulations. The Moral IFC amended those regulations further, and added an additional rule at 45 CFR part 147.133. These final rules adopt as final, and further amend, the amendments made by the Moral IFC. The Departments do so in conjunction with the amendments made in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. These rules provide an exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4), section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, for certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process by making the accommodation applicable to organizations with such convictions as an option. The exemption applies to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action has been taken to provide for participation in the health insurance market by certain entities or individuals in a manner free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to ensure the preventive services coverage requirement is implemented in a way consistent with longstanding federal conscience statutes, to prevent lawsuits of the kind that were filed against the Departments when the expanded exemption in these final rules was not offered, and for the other reasons discussed above.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these final rules, we believe it to be small.

With respect to the exemption for nonprofit organizations with objections based on moral convictions, as noted

above, the Departments are aware of two small nonprofit organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree with their opposition to the nature of certain contraceptives subject to coverage under the Mandate.[73] One of them has obtained a permanent injunction against any regulations implementing the contraceptive Mandate, and so will not be affected by these final rules. Based on comments submitted in response to rulemakings prior to the Moral and Religious IFCs, the Departments believe that at least one other similar entity exists.[74] However, the Departments do not know how many similar entities exist and are currently unable to estimate the number of such entities. Lacking other information, we assume that the number is small. The Departments estimate it to be less than 10 and assume the exemption will be used by nine nonprofit entities.

The Departments also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with the conclusion in previous regulations that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (See 76 FR 46625 and 78 FR 39889). The Departments reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception and without requiring that such entities actually oppose contraception in order to be exempt (in contrast, the exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to contraceptive coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, the Departments relied on the assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is appropriate with respect to the expanded exemption for nonprofit organizations with objections based on moral convictions. To the knowledge of the Departments, the vast majority of organizations objecting to the Mandate assert objections based on religious beliefs. The only nonprofit organizations of which they are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It is possible that the exemption for nonprofit organizations with moral convictions in these final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under the Departments' previous regulations that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.[75] Although the Departments are unable to find sufficient data on this issue, we believe that there are far fewer nonprofit organizations opposed to contraceptive coverage on the basis of moral convictions than there are houses of worship or integrated auxiliaries with religious objections to such coverage. Based on the limited data available, the Departments believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose certain contraceptive coverage. Therefore, the Departments expect that the moral exemption for nonprofit entities will have a minimal effect of reducing contraceptive coverage with respect to employees who want such coverage.

These rules extend the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and make exempt entities with moral objections eligible to avail themselves of the accommodation. The Departments are not aware of any institutions of higher education with this kind of non-religious moral convictions. Moreover, the Departments believe the overall number of entities that would object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education. Public comments did not reveal the existence of any institutions of higher education with such moral convictions. Therefore, for the purposes of estimating the anticipated effect of these final rules on contraceptive coverage of women who wish to receive such coverage, the Departments assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no other entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might come into existence, based on reasons similar to those given above for why the exemptions and accommodations are extended to other entities.

The Departments believe that the exemption for issuers with objections based on moral convictions will not result in a distinct effect on contraceptive coverage for women who wish to receive it, because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein, or in the companion final rules concerning religious beliefs published elsewhere in today's **Federal Register**. The exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The moral exemption will also cover for-profit entities that do not have publicly traded ownership interests and that have non-religious moral objections to the Mandate, if such entities exist. Some commenters agreed that the impact of these final rules would be no more than the Departments estimated in the Moral IFC, and some commenters stated the impact would be much smaller. Other commenters disagreed, suggesting that the expanded exemptions risked removing contraceptive coverage from more than 55 million women receiving the benefits of the preventive services Guidelines, or even risked removing contraceptive coverage from over 100 million women. Some commenters cited studies indicating that, nationally, unintended

[73] Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

[74] See, for example, Americans United for Life ("AUL") Comment on CMA-9992-IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496*, and AUL Comment on CMS-9968-P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115*.

[75] *Cf., for example*, Frank Newport, "Americans, Including Catholics, Say Birth Control Is Morally OK," Gallup, (May 22, 2012), *http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx* ("Eighty-two percent of U.S. Catholics say birth control is morally acceptable").

pregnancies have large public costs, and the Mandate overall led to large out-of-pocket savings for women. These general comments did not, however, substantially assist the Departments in estimating the number of women that would potentially be affected by these exemptions for moral convictions specifically, or among them, how many unintended pregnancies would result, how many of the affected women would nevertheless use contraceptives not covered under the health plans of their objecting employers and, thus, be subject to the estimated transfer costs, or instead, how many women might avoid unintended pregnancies by changing their activities in other ways besides using contraceptives.

Some of the comments opposing these exemptions assert that they will lead to a large number of entities dropping contraceptive coverage. The Departments disagree; they are aware of only two entities that hold non-religious moral convictions against contraceptive coverage. Both only hire employees that share their beliefs, and one will not be affected by these final rules because it is protected by an injunction from any regulations implementing the contraceptive Mandate. Commenters cited no other specific entities that might assert these moral convictions, and did not provide better data to estimate how many entities might exist. Likewise, the Departments find it unlikely that any of the vast majority of entities that covered contraceptives before this Mandate was announced in 2011 would terminate such coverage because of these exemptions based on moral convictions. The Departments also find it unlikely that a significant number of for-profit entities, whose plans include a significant number of women, omitted contraceptive coverage before the ACA on the basis of objections grounded in non-religious moral convictions, and would claim an exemption under these final rules. No such entities, or data concerning such entities, were identified by public commenters, nor are the Departments aware of any involved in litigation over the Mandate.

Numerous for-profit entities claiming religious objections have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—and both were nonprofit organizations. Among the general public, polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they believe in God.[76] Among non-religious persons, only a very small percentage of the population appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.[77] Combined, this suggests that 0.2 percent of Americans at most[78] might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. The Departments have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral convictions set forth in these final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, the Departments assume that some similar for-profit entities with non-religious moral objections exist. But the Departments expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities without publicly traded ownership interests and with sincere moral objections to the Mandate, the Departments expect that fewer than 10 entities, if any, will do so—so the Departments assume nine for-profit entities will use the exemption in these final rules.

The moral exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) to obtain an estimate of the number of policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.[79] The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known how many employees would be employed by the for-profit employers that might claim this exemption, but as discussed above these final rules do not include publicly traded companies, and both of the two nonprofit entities that challenged the Mandate based on moral objections included fewer than five policyholders in their group plans. Therefore, the Departments assume that the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For 9 entities, the total number of policyholders would be approximately 81. DOL estimates that for each policyholder, there is approximately one dependent.[80] This amounts to approximately 162 covered persons. Census data indicate that women of childbearing age, *i.e.*, women aged 15 to 44, comprise 20.2 percent of the general population.[81] This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.[82] Thus, the Departments estimate that approximately 15 women may incur contraceptive costs due to for-profit entities using the expanded moral exemption provided for in these final rules.[83] In the companion final

[76] Frank Newport, "Most Americans Still Believe in God," Gallup (June 29, 2016), *http://www.gallup.com/poll/193271/americans-believe-god.aspx*.

[77] Pew Research Center, "Where the Public Stands on Religious Liberty vs. Nondiscrimination," Pew Research Center, 26 (Sept. 28, 2016), *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf*.

[78] The study defined religiously "unaffiliated" as agnostic, atheist or "nothing in particular", *id.* at 8, as distinct from several versions of Protestants, or Catholics. "Nothing in particular" might have included some theists.

[79] "Health Insurance Coverage Bulletin," Dept. of Labor (June 28, 2016), Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf*. Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey—Insurance.

[80] "Health Insurance Coverage Bulletin" Dept. of Labor" (June 28, 2016), Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf*.

[81] U.S. Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf*. The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." Women's Preventive Services Guidelines, HRSA (last reviewed Oct. 2017), *https://www.hrsa.gov/womensguidelines/*; *see also* 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. *See, e.g.*, "Contraceptive Use in the United States," The Guttmacher Institute (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states*.

[82] *See* "Contraceptive Use in the United States," The Guttmacher Institute (Sept. 2016), *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states*.

[83] The Departments note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be

Continued

rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, in health plans that cover contraception, is $584. Consequently, the Departments estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded moral exemption in these final rules is approximately $8,760.

The Departments estimate that these final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will avail themselves of the accommodation, although the Departments wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to its plan participants and beneficiaries. While these final rules make it legal for issuers to offer insurance coverage that omits contraceptives to/for exempt entities and individuals, these final rules do not require issuers to do so. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, the Departments do not anticipate that these final rules will result in any burden from such entities acting to revoke their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the exemptions finalized in these final rules. The Departments acknowledge uncertainty in the estimate and, therefore, conducted a second analysis using an alternative framework, which is set forth in the companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**, with reference to the analysis conducted in the Religious IFC. Under either estimate, these final rules are not deemed to be economically significant.

covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion —and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

The Departments reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

B. Special Analyses—Department of the Treasury

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Department of the Treasury and the Office of Management and Budget regarding review of tax regulations.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) imposes certain requirements with respect to federal regulations that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The Moral IFC was a set of interim final rules with comment, and in these final rules, the Departments finalize the Moral IFC with certain changes based on public comments. The Moral IFC was exempt from the notice and comment requirements of the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA did not apply to the Moral IFC. These final rules are, however, issued after a notice and comment period.

The Departments carefully considered the likely impact of the rules on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, by exempting from the Mandate small businesses and nonprofit organizations with moral objections to some or all contraceptives and/or sterilization—businesses and organizations which would otherwise be faced with the dilemma of complying with the Mandate (and violating their moral convictions), or of following their moral convictions and incurring potentially significant financial penalties for noncompliance—the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** and solicit public comment before a collection of information is submitted to the Office of Management and Budget (OMB) for review and approval. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

The Departments estimate that these final rules will not result in additional burdens not accounted for as set forth in companion final rules concerning religious beliefs issued contemporaneously with these final rules and published elsewhere in today's **Federal Register**. As discussed there, rules covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(e)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burden related to these information collection requirements (ICRs) received emergency review and approval under OMB Control Number 0938–1344. They have been resubmitted to OMB in conjunction with this final rule and are pending re-approval.

As discussed above, however, the Departments assume that no entities with non-religious moral objections to the Mandate will use the accommodation. The Departments know that no such entities were eligible for it until now, so that no entity possesses an accommodated status that would need to be revoked. Therefore, the Departments believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1344, as described in the final rules concerning religious beliefs issued contemporaneously with these final rules.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. In an effort to consolidate the number of information collections the Department is combining OMB control numbers 1210–0150 and 1210–0152 under OMB control number 1210–0150 and discontinuing OMB control number 1210–0152.

A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov.* PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these final rules make entities with certain moral convictions eligible for the accommodation, the Department assumes (1) that no entities will use the accommodation rather than the exemption, and (2) entities using the moral exemption would not have to revoke an accommodation, because they previously were not eligible for it. Therefore, the Department believes these final rules do not involve additional burden not accounted for under OMB control number 1210–0150, which is published elsewhere in today's issue of the **Federal Register** in connection with the companion Religious Exemption and Accommodation Preventive Health Service final rule. The Department will publish a notice informing the public of OMB's action with respect to the Department's submission of the ICRs under OMB control number 1210–0150.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, "[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [Affordable Care] Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." In addition, agencies are directed to "take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market." The Moral IFC and these final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), the Departments have estimated the costs and cost savings attributable to these rules. As discussed in more detail in the preceding analysis, these final rules lessen incremental reporting costs.[84] However, in order to avoid double-counting with the Moral IFC, which has already been tallied as an E.O. 13771 deregulatory action, this finalization of the IFC's policy is not considered a deregulatory action under the Executive Order.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) (Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any 1 year." In 2018, that threshold is approximately $150 million. For purposes of the Unfunded Mandates Reform Act, the Moral IFC and these final rules do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of $150 million or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

IV. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

[84] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to these final rules' medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 30, 2018.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 29th day of October, 2018.

Preston Rutledge,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: October 17, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 18, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§ 54.9815–2713 [Amended]

■ 2. Section 54.9815–2713, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraph (a)(1)(iv) by removing the reference "147.131 and 147.132" and adding in its place the reference "147.131, 147.132, and 147.133".

§ 54.9815–2713A [Amended]

■ 3. Section 54.9815–2713A, as amended elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (a)(1) by removing "or (ii)" and adding in its place "or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)";

■ b. In paragraph (a)(2) by removing the reference "147.132(a)" and adding in its place the reference "147.132(a) or 147.133(a)";

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ d. In paragraph (b)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ f. In paragraph (c)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133"; and

■ g. In paragraph (c)(2) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133".

DEPARTMENT OF LABOR

Employee Benefits Security Administration

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ For the reasons set forth in the preamble, the Department of Labor adopts, as final, the interim final rules amending 29 CFR part 2590, published October 13, 2017 (82 FR 47838), without change.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

■ For the reasons set forth in the preamble, the Department of Health and Human Services adopts as final the interim final rules amending 45 CFR part 147 published on October 13, 2017 (82 FR 47838) with the following changes:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 4. The authority citation for part 147, as revised elsewhere in this issue of the **Federal Register**, continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92, as amended.

■ 5. Section 147.133 is amended by revising paragraph (a)(1) introductory text, (a)(1)(ii), (a)(2), and (b) to read as follow:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) * * *

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, to the extent of the objections specified below. Thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

* * * * *

(ii) An institution of higher education as defined in 20 U.S.C. 1002, which is non-governmental, in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health

insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

* * * * *

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects, based on its sincerely held moral convictions, to its establishing, maintaining, providing, offering, or arranging for (as applicable):

(i) Coverage or payments for some or all contraceptive services; or

(ii) A plan, issuer, or third party administrator that provides or arranges such coverage or payments.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any group health plan sponsor (with respect to an individual) or individual, as applicable, who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions. Under this exemption, if an individual objects to some but not all contraceptive services, but the issuer, and as applicable, plan sponsor, are willing to provide the plan sponsor or individual, as applicable, with a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option that omits all contraceptives, and the individual agrees, then the exemption applies as if the individual objects to all contraceptive services.

* * * * *

[FR Doc. 2018–24514 Filed 11–7–18; 4:15 pm]

BILLING CODE 4830–01–P; 4510–29–P; 4120–01–P

www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm592778.htm. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by April 25, 2018, 5 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when their registration has been received. If time and space permit, onsite registration on the day of the public workshop will be provided beginning an hour prior to the start of the meeting.

If you need special accommodations due to a disability, please contact Nicole Wolanski, at 301–796–6570, or *OOPDOrphanEvents@fda.hhs.gov* no later than April 25, 2018.

An agenda for the workshop and any other background materials will be made available 5 days before the workshop at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm592778.htm.*

Streaming Webcast of the Public Workshop: For those unable to attend in person, FDA will provide a live webcast of the workshop. To register for the streaming webcast of the public workshop, please visit the following website by May 8, 2018: *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm592778.htm.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/NewsEvents/MeetingsConferencesWorkshops/ucm592778.htm.*

Dated: February 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–03961 Filed 2–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: Applicable as of December 29, 2017, HRSA updated the HRSA-supported Women's Preventive Services Guidelines for purposes of health insurance coverage for preventive services that address health needs specific to women based on clinical recommendations from the Women's Preventive Services Initiative. This 2017 update adds two additional services—Screening for Diabetes Mellitus after Pregnancy and Screening for Urinary Incontinence—to the nine preventive services included in the 2016 update to the HRSA-supported Women's Preventive Services Guidelines. The nine services included in the 2016 update are as follows: Breast Cancer Screening for Average Risk Women, Breastfeeding Services and Supplies, Screening for Cervical Cancer, Contraception, Screening for Gestational Diabetes Mellitus, Screening for Human Immunodeficiency Virus Infection, Screening for Interpersonal and Domestic Violence, Counseling for Sexually Transmitted Infections, and Well-Woman Preventive Visits. This notice serves as an announcement of the decision to update the guidelines as listed below. Please see *https://www.hrsa.gov/womens-guidelines/index.html* for additional information.

FOR FURTHER INFORMATION CONTACT: Kimberly C. Sherman, Maternal and Child Health Bureau, HRSA at phone: (301) 443–0543; email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The complete set of updated 2017 HRSA-supported Women's Preventive Services Guidelines includes those that were accepted by the Acting HRSA Administrator on December 20, 2016, as well as two new services, Screening for Diabetes Mellitus After Pregnancy and Screening for Urinary Incontinence. For a complete listing and detailed information about the December 20, 2016, updates, please see *https://www.federalregister.gov/documents/2016/12/27/2016-31129/updating-the-hrsa-supported-womens-preventive-services-guidelines.* In addition, the December 20, 2016, updates, including information related to coverage of contraceptive services and exemption for objecting organizations from requirements related to the provision of contraceptive services, can be found at *https://www.hrsa.gov/womens-guidelines-2016/index.html.* Information regarding the two new services that were accepted by the HRSA Administrator on December 29, 2017, is set out below:

1. Screening for Diabetes Mellitus After Pregnancy

The Women's Preventive Services Initiative recommends women with a history of gestational diabetes mellitus (GDM) who are not currently pregnant and who have not previously been diagnosed with type 2 diabetes mellitus should be screened for diabetes mellitus. Initial testing should ideally occur within the first year postpartum and can be conducted as early as 4–6 weeks postpartum.

Women with a negative initial postpartum screening test result should be rescreened at least every 3 years for a minimum of 10 years after pregnancy. For women with a positive postpartum screening test result, testing to confirm the diagnosis of diabetes is indicated regardless of the initial test (*e.g.,* oral glucose tolerance test, fasting plasma glucose, or hemoglobin A1c). Repeat testing is indicated in women who were screened with hemoglobin A1c in the first six months postpartum regardless of the result (see Implementation Considerations below).

2. Screening for Urinary Incontinence

The Women's Preventive Services Initiative recommends screening women for urinary incontinence annually. Screening should ideally assess whether women experience urinary incontinence and whether it impacts their activities and quality of life. The Women's Preventive Services Initiative recommends referring women for further evaluation and treatment if indicated.

HRSA-Supported Women's Preventive Services Guidelines

The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from an HHS commissioned study by the Institute of Medicine, now known as the National

Academy of Medicine (NAM). Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. To address these, HRSA awarded a 5-year cooperative agreement in March 2016 to convene a coalition of clinician, academic and consumer-focused health professional organizations and conduct a scientifically rigorous review to develop recommendations for updated Women's Preventive Services Guidelines in accordance with the model created by the NAM *Clinical Practice Guidelines We Can Trust*. The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative.

Under section 2713 of the Public Health Service Act, non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose. Non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing for preventive services listed in the updated HRSA-supported guidelines (which include the nine preventive services set out in the 2016 update, as well as the two services added in this update) beginning with the first plan year (in the individual market, policy year) that begins on or after December 29, 2018.

Dated: February 20, 2018.

George Sigounas,

Administrator.

[FR Doc. 2018–03840 Filed 2–26–18; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–16–366 Dual Purpose with Dual Benefit: Research in Biomedicine and Agriculture.

Date: March 21–22, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tera Bounds, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3214, MSC 7808, Bethesda, MD 20892, 301–435–2306, *boundst@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict.

Date: March 21, 2018.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3142, Bethesda, MD 20892, 301–435–2309, *fothergillke@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: The Biostatistical Methods and Research Design.

Date: March 21, 2018.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ping Wu, Ph.D., Scientific Review Officer, HDM IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, Bethesda, MD 20892, 301–451–8428, *wup4@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: AIDS and Related Research.

Date: March 22, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

Contact Person: Robert Freund, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5216, MSC 7852, Bethesda, MD 20892, 301–435–1050, *freundr@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Fellowship: Infectious Diseases and Microbiology.

Date: March 22–23, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW, Washington, DC 20001.

Contact Person: Tamara Lyn McNealy, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3188, Bethesda, MD 20747, 301–827–2372, *tamara.mcneal y@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Cancer Health Disparities.

Date: March 22, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Janet M. Larkin, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5142, MSC 7840, Bethesda, MD 20892, 301–806–2765, *larkinja@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Innovative Immunology.

Date: March 22, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Andrea Keane-Myers, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4218, Bethesda, MD 20892, 301–435–1221, *andrea.keane-myers@nih.gov*.

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Discovery and Development of Therapeutics Study Section.

Date: March 22, 2018.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW, Washington, DC 20037.

Contact Person: Shiv A. Prasad, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5220, MSC 7852, Bethesda, MD 20892, 301–443–5779, *prasads@csr.nih.gov*.

Name of Committee: AIDS and Related Research Integrated Review Group; NeuroAIDS and other End-Organ Diseases Study Section.

Date: March 22, 2018.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9827]

RIN 1545–BN92

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB83

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9940–IFC]

RIN 0938–AT20

Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs and moral convictions. These interim final rules expand exemptions to protect religious beliefs for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also leave the "accommodation" process in place as an optional process for certain exempt entities that wish to use it voluntarily. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES: *Effective date:* These interim final rules and temporary regulations are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by "Preventive Services," may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9940–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9940–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492–4305 or *marketreform@cms.hhs.gov* for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's Web site (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Congress has consistently sought to protect religious beliefs in the context of health care and human services, including health insurance, even as it has sought to promote access to health services.[1] Against that backdrop,

[1] See, for example, 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their "religious beliefs or moral convictions"); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS, and Education, and Related Agencies Appropriations Act). Public Law 115–31 (protecting any "health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of "the provision of

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, "with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by" by HRSA (the "Guidelines"). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,[2] while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, "the Departments" [3])—exercised the same discretion to allow exemptions to those requirements. Through rulemaking, including three interim final rules, the Departments allowed exemptions and accommodations for certain religious objectors where the Guidelines require coverage of contraceptive services. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the "contraceptive Mandate," or the "Mandate") as being inconsistent with various legal protections, including the Religious Freedom Restoration Act, 42 U.S.C. 2000bb–1. Much of that litigation continues to this day.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as the interests served by the existing Guidelines, regulations, and accommodation process; [4] the extensive litigation; Executive Order 13798, "Promoting Free Speech and Religious Liberty" (May 4, 2017); protection of the free exercise of religion in the First Amendment and by Congress in the Religious Freedom Restoration Act of 1993; Congress' history of providing protections for religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under section 2713(a)(4) of the PHS Act; the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; the regulatory process and comments submitted in various requests for public comments (including in the Departments' 2016 Request for Information).

In light of these factors, the Departments issue these new interim final rules to better balance the Government's interest in ensuring coverage for contraceptive and sterilization services in relation to the Government's interests, including as reflected throughout Federal law, to provide conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts, and to minimize burdens in our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, "[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact" and that "[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the HHS."

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS Act requires coverage without cost sharing for "such additional" women's preventive care and screenings "as provided for" and "supported by" guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

contraceptive coverage by health insurance plans" in the District of Columbia, "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions."); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions"); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their "religious or conscientious commitment to offer only natural family planning"); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on "religious beliefs or moral objections"); 42 U.S.C. 290kk–1 (protecting the religious character of organizations participating in certain programs and the religious freedom of beneficiaries of the programs); 42 U.S.C. 300x–65 (protecting the religious character of organizations and the religious freedom of individuals involved in the use of government funds to provide substance abuse services); 42 U.S.C. 604a (protecting the religious character of organizations and the religious freedom of beneficiaries involved in the use of government assistance to needy families); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on "conscience" as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 5106i (prohibiting certain Federal statutes from being construed to require that a parent or legal guardian provide a child any medical service or treatment against the religious beliefs of the parent or legal guardian); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on "religious beliefs or moral convictions"); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); also, see 8 U.S.C. 1182(g) (protecting vaccination objections by "aliens" due to "religious beliefs or moral convictions"); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on "moral or religious convictions"); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their "religious or moral objection").

[2] This document's references to "contraception," "contraceptive," "contraceptive coverage," or "contraceptive services" generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

[3] Note, however, that in sections under headings listing only two of the three Departments, the term "Departments" generally refers only to the two Departments listed in the heading.

[4] In this document, we generally use "accommodation" and "accommodation process" interchangeably.

The Departments have consistently interpreted section 2714(a)(4) PHS Act's grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA's Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women's preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act's reference to "comprehensive guidelines supported by HRSA for purposes of this paragraph" to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines "supported by HRSA for purposes of this paragraph," the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from "the other guidelines referenced in section 2713(a) of the PHS Act, which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients." Id. Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4) of the PHS Act, the Departments have previously promulgated regulations defining the scope of permissible exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92)

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. Congress did not intend to require entirely uniform coverage of preventive services (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 of the PHS Act for grandfathered plans. In contrast, this exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing "particularly significant protections." (75 FR 34540). Those provisions include: Section 2704 of the PHS Act, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708 of the PHS Act, which prohibits excessive waiting periods (as of January 1, 2014); section 2711 of the PHS Act, which relates to lifetime limits; section 2712 of the PHS Act, which prohibits rescission of health insurance coverage; section 2714 of the PHS Act, which extends dependent coverage until age 26; and section 2718 of the PHS Act, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.[5] As the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." *Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments' interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments' own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that "longstanding Federal laws to protect conscience * * * remain intact," including laws that protect religious beliefs (and moral convictions) from certain requirements in the health care context. While the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect religious beliefs regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in accordance with the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, "Clinical Preventive Services for Women, Closing the Gaps" (IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.[6]

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of "contraceptives" certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,[7] the IOM's recommendation included several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason

[5] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[6] Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings "with respect to women," the Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

[7] FDA's guide "Birth Control: Medicines To Help You," specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and "may also work * * * by preventing attachment (implantation) to the womb (uterus)" of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

distinct from whether they also oppose contraception or sterilization.

One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He argued that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by the United States Preventive Services Task Force (USPSTF), HRSA's Bright Futures Project, and the Advisory Committee on Immunization Practices (ACIP) leads to lower rates of disability or disease and increased rates of well-being. He further argued that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered," and that "the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy." Dr. LoSasso also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.[8] (IOM 2011 at 231–32). In its response to Dr. LoSasso, the other 15 committee members stated, in part, that "At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions."

2. HRSA's 2011 Guidelines and the Departments' Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women's preventive services, adopting the recommendations of the IOM *https://www.hrsa.gov/womensguidelines/*. The Guidelines included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider.

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specify that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.[9] The 2011 interim final rules defined an exempt "religious employer" narrowly as one that: (1) Had the inculcation of religious values as its purpose; (2) primarily employed persons who shared its religious tenets; (3) primarily served persons who shared its religious tenets; and (4) was a nonprofit organization, as described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Those relevant sections of the Code include only churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of a religious order. The practical effect of the rules' definition of "religious employer" was to create potential uncertainty about whether employers, including many of those houses of worship or their integrated auxiliaries, would fail to qualify for the exemption if they engaged in outreach activities toward persons who did not share their religious tenets.[10] As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some "States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services." (76 FR 46623). That same day, HRSA exercised the discretion described in the 2011 interim final rules to provide the exemption.

3. The Departments' Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of "religious employer" in the 2011 interim final rules without modification (2012 final regulations).[11] (77 FR 8725). The exemption did not require religious employers to file any certification form or comply with any other information collection process.

Contemporaneous with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).[12] The guidance provided that the temporary safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. The temporary safe harbor did not apply to for-profit entities. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve "two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services." (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of "religious employer" for purposes of the religious employer

[8] The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

[9] The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011 (76 FR 46621).

[10] See, for example, Comments of the United States Conference of Catholic Bishops on Interim Final Rules on Preventive Services, File Code CMS–9992–IFC2 (Aug. 31, 2011).

[11] The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

[12] Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: *http://www.lb7.uscourts.gov/documents/12cv3932.pdf*. The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled "Student Health Insurance Coverage" published March 21, 2012 (77 FR 16457).

exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer (1) have the inculcation of religious values as its purpose, (2) primarily employ persons who share its religious tenets, and (3) primarily serve persons who share its religious tenets.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible religious nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations "may be less likely than" employees of exempt houses of worship and integrated auxiliaries to share their employer's faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization's plan—and without any cost to the eligible organization.[13] In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries.

On August 15, 2012, the Departments also extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

[13] The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations "does not undermine the governmental interests furthered by the contraceptive coverage requirement." (78 FR 39874). But, like the 2013 NPRM, the July 2013 regulations assumed that "[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection" to contraceptives (*Id.*).

The July 2013 regulations also finalized an accommodation for eligible organizations. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization's plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect.[14] With respect to fully insured group health plans, the issuer was expected to bear the cost of such payments,[15] and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations.

With respect to self-insured group health plans, the July 2013 final regulations specified that the self-certification was an instrument under which the plan was operated and that it obligated the third party administrator to provide or arrange for contraceptive coverage by operation of section 3(16) of ERISA. The regulations stated that, by submitting the self-certification form, the eligible organization "complies" with the contraceptive coverage requirement and does not have to contract, arrange, pay, or refer for contraceptive coverage. See, for example, Id. at 39874, 39896. Consistent with these statements, the Departments, through the Department of Labor, issued a self-certification form, EBSA Form 700. The form stated, in indented text labeled as a "Notice to Third Party Administrators of Self-Insured Health Plans," that "[t]he obligations of the third party administrator are set forth in 26 CFR 54.9815–2713A, 29 CFR 2510.3–16, and 29 CFR 2590.715–2713A" and concluded, in unindented text, that "[t]his form is an instrument under which the plan is operated."

The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. The guidance extending the safe harbor included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary safe harbor if no prior form had been submitted.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others. Religious plaintiffs principally argued that the Mandate violated the Religious Freedom Restoration Act of 1993 (RFRA) by forcing them to provide coverage or payments for sterilization and contraceptive services, including what they viewed as early abortifacient items, contrary to their religious beliefs. Based on this claim, in July 2012 a

[14] See also 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was $33 million.

[15] "[P]roviding payments for contraceptive services is cost neutral for issuers." (78 FR 39877).

Federal district court issued a preliminary injunction barring the Departments from enforcing the Mandate against a family-owned business. *Newland* v. *Sebelius*, 881 F. Supp. 2d. 1287 (D. Colo. 2012). Multiple other courts proceeded to issue similar injunctions against the Mandate. although a minority of courts ruled in the Departments' favor. *Compare Tyndale House Publishers, Inc.* v. *Sebelius*, 904 F. Supp. 2d 106 (D.D.C. 2012), and *The Seneca Hardwood Lumber Company, Inc.* v. *Sebelius* (sub nom *Geneva Coll.* v. *Sebelius)*, 941 F. Supp. 2d 672 (W.D. Pa. 2013), with *O'Brien* v. *U.S. Dep't of Health & Human Servs.*, 894 F. Supp. 2d 1149 (E.D. Mo. 2012).

A circuit split swiftly developed in cases filed by religiously motivated for-profit businesses, to which neither the religious employer exemption nor the eligible organization accommodation (as then promulgated) applied. Several for-profit businesses won rulings against the Mandate before the Unites States Court of Appeals for the Tenth Circuit, sitting en banc, while similar rulings against the Departments were issued by the Seventh and District of Columbia (DC) Circuits. *Hobby Lobby Stores, Inc.* v. *Sebelius*, 723 F.3d 1114 (10th Cir. 2013); *Korte* v. *Sebelius*, 735 F.3d 654 (7th Cir. 2013); *Gilardi* v. *U.S. Dep't of Health & Human Servs.*, 733 F.3d 1208 (D.C. Cir. 2013). The Third and Sixth Circuits disagreed with similar plaintiffs, and in November 2013 the U.S. Supreme Court granted certiorari in *Hobby Lobby* and *Conestoga Wood Specialties Corp.* v. *Secretary of U.S. Department of Health & Human Services*, 724 F.3d 377 (3d Cir. 2013), to resolve the circuit split.

On June 30, 2014, the Supreme Court ruled against the Departments and held that, under RFRA, the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[16] *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Court held that the "contraceptive mandate 'substantially burdens' the exercise of religion" as applied to employers that object to providing contraceptive coverage on religious grounds, and that the plaintiffs were therefore entitled to an exemption unless the Mandate was the least restrictive means of furthering a compelling governmental interest. *Id.* at 2775. The Court observed that, under the compelling interest test of RFRA, the Departments could not rely on interests "couched in very broad terms, such as promoting 'public health' and 'gender equality,' but rather, had to demonstrate that a compelling interest was served by refusing an exemption to the "particular claimant[s]" seeking an exemption. *Id.* at 2779. Assuming without deciding that a compelling interest existed, the Court held that the Government's goal of guaranteeing coverage for contraceptive methods without cost sharing could be achieved in a less restrictive manner. The Court observed that "[t]he most straightforward way of doing this would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections." *Id.* at 2780. The Court also observed that the Departments had "not provided any estimate of the average cost per employee of providing access to these contraceptives," nor "any statistics regarding the number of employees who might be affected because they work for corporations like Hobby Lobby, Conestoga, and Mardel". *Id.* at 2780–81. But the Court ultimately concluded that it "need not rely on the option of a new, government-funded program in order to conclude that the HHS regulations fail the least-restrictive means test" because "HHS itself ha[d] demonstrated that it ha[d] at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs." *Id.* at 2781–82. The Court explained that the "already established" accommodation process available to nonprofit organizations was a less-restrictive alternative that "serve[d] HHS's stated interests equally well," although the Court emphasized that its ruling did not decide whether the accommodation process "complie[d] with RFRA for purposes of all religious claims". *Id.* at 2788–82.

Meanwhile, another plaintiff obtained temporary relief from the Supreme Court in a case challenging the accommodation under RFRA. Wheaton College, a Christian liberal arts college in Illinois, objected that the accommodation was a compliance process that rendered it complicit in delivering payments for abortifacient contraceptive services to its employees. Wheaton College refused to execute the EBSA Form 700 required under the July 2013 final regulations. It was denied a preliminary injunction in the Federal district and appellate courts, and sought an emergency injunction pending appeal from the Unites States Supreme Court on June 30, 2014. On July 3, 2014, the Supreme Court issued an interim order in favor of the College, stating that, "[i]f the [plaintiff] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing [the Mandate] against the [plaintiff] . . . pending final disposition of appellate review." *Wheaton College* v. *Burwell*. 134 S. Ct. 2806, 2807 (2014). The order stated that Wheaton College did not need to use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for injunctive relief. *Id.*

In response to this litigation, on August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of the Department of Health and Human Services that an eligible organization had religious objections to coverage of all or a subset of contraceptive services. (79 FR 51092). In response to *Hobby Lobby*. the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations. (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption, and neither added a certification requirement for exempt entities.

In October 2014, based on an interpretation of the Supreme Court's interim order, HHS deemed Wheaton College as having submitted a sufficient notice to HHS. HHS conveyed that interpretation to the DOL, so as to trigger the accommodation process.

On July 14, 2015. the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The preamble to the July 2015 final regulations stated that, through the accommodation, payments

[16] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. See 134 S. Ct. at 2774.

for contraceptives and sterilization would be provided in a way that is "seamless" with the coverage that eligible employers provide to their plan participants and beneficiaries. *Id.* at 41328. The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

When an eligible organization maintains an insured group health plan or student health plan and provides the alternative notice, the July 2015 final regulations provide that HHS will inform the health insurance issuer of its obligations to cover contraceptive services to which the eligible organization objects. Where an eligible organization maintains a self-insured plan under ERISA and provides the alternative notice, the regulations provide that DOL will work with HHS to send a separate notification to the self-insured plan's third party administrator(s). The regulations further provide that such notification is an instrument under which the plan is operated for the purposes of section 3(16) of ERISA, and the instrument would designate the third party administrator as the entity obligated to provide or arrange for payments for contraceptives to which the eligible organization objects. The July 2015 final regulations continue to apply the amended notice requirement to eligible organizations that sponsor church plans exempt from ERISA pursuant to section 4(b)(2) of ERISA, but acknowledge that, with respect to the operation of the accommodation process, section 3(16) of ERISA does not provide a mechanism to impose an obligation to provide contraceptive coverage as a plan administrator on those eligible organizations' third party administrators. (80 FR 41323).

Meanwhile, a second split among Federal appeals courts had developed involving challenges to the Mandate's accommodation. Many religious nonprofit organizations argued that the accommodation impermissibly burdened their religious beliefs because it utilized the plans the organizations themselves sponsored to provide services to which they objected on religious grounds. They objected to the self-certification requirement on the same basis. Federal district courts split in the cases, granting preliminary injunction motions to religious groups in the majority of cases, but denying them to others. In most appellate cases, religious nonprofit organizations lost their challenges, where the courts often concluded that the accommodation imposed no substantial burden on their religious exercise under RFRA. For example, *Priests for Life* v. *U.S. Dep't of Health and Human Servs.*, 772 F. 3d 229 (D.C. Cir. 2014); *Little Sisters of the Poor Home for the Aged* v. *Burwell*, 794 F.3d 1151 (10th Cir. 2015); *Geneva Coll.* v. *Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422 (3d Cir. 2015). But the Eighth Circuit disagreed and ruled in favor of religious nonprofit employers. *Dordt College* v. *Burwell*, 801 F.3d 946, 949–50 (8th Cir. 2015) (relying on *Sharpe Holdings, Inc.* v. *U.S. Dep't of Health & Human Servs.*, 801 F.3d 927 (8th Cir. 2015)).

On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik* v. *Burwell*. The Court held oral argument on March 23, 2016, and, after the argument, asked the parties to submit supplemental briefs addressing "whether and how contraceptive coverage may be obtained by petitioners' employees through petitioners' insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees". In a brief filed with the Supreme Court on April 12, 2016, the Government stated on behalf of the Departments that the accommodation process for eligible organizations with insured plans could operate without any self-certification or written notice being submitted by eligible organizations.

On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik*, vacating the judgments of the Courts of Appeals and remanding the cases "in light of the substantial clarification and refinement in the positions of the parties" in their supplemental briefs. (136 S. Ct. 1557, 1560 (2016).) The Court stated that it anticipated that, on remand, the Courts of Appeals would "allow the parties sufficient time to resolve any outstanding issues between them." *Id.* The Court also specified that "the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice" while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, some meetings were held between attorneys for the Government and for the plaintiffs in those cases. Separately, at various times after the Supreme Court's remand order, HHS and DOL sent letters to the issuers and third party administrators of certain plaintiffs in *Zubik* and other pending cases, directing the issuers and third party administrators to provide contraceptive coverage for participants in those plaintiffs' group health plans under the accommodation. The Departments also issued a Request for Information (RFI) on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016.

On December 20, 2016, HRSA updated the Guidelines via its Web site, *https://www.hrsa.gov/womensguidelines2016/index.html*. HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the contraceptive method). They also specified that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women's Preventive Services' Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process.

On January 9, 2017, the Departments issued a document entitled, "FAQs About Affordable Care Act Implementation Part 36" (FAQ).[17] The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. Thus, the

[17] Available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf*.

litigation on remand from the Supreme Court remains unresolved.

A separate category of unresolved litigation involved religious employees as plaintiffs. For example, in two cases, the plaintiff-employees work for a nonprofit organization that agrees with the employees (on moral grounds) in opposing coverage of certain contraceptives they believe to be abortifacient, and that is willing to offer them insurance coverage that omits such services. See *March for Life* v. *Burwell,* 128 F. Supp. 3d 116 (D.D.C. 2015); *Real Alternatives,* 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). In another case, the plaintiff-employees work for a State government entity that the employees claim is willing, under State law, to provide a plan omitting contraception consistent with the employees' religious beliefs. See *Wieland* v. *HHS,* 196 F. Supp. 3d 1010 (E.D. Mo. 2016). Those and similar employee-plaintiffs generally contend that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from their willing employer or in the individual market, because the Departments offer no exemptions encompassing either circumstance. Such challenges have seen mixed success. Compare, for example, *Wieland,* 196 F. Supp. 3d at 1020 (concluding that the Mandate violates the employee plaintiffs' rights under RFRA and permanently enjoining the Departments) and *March for Life,* 128 F. Supp. 3d at 133–34 (same), with *Real Alternatives,* 2017 WL 3324690 at *18 (affirming dismissal of employee plaintiffs' RFRA claim).

On May 4, 2017, the President issued an "Executive Order Promoting Free Speech and Religious Liberty." Regarding "Conscience Protections with Respect to Preventive-Care Mandate," that order instructs "[t]he Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services [to] consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code."

II. RFRA and Government Interests Underlying the Mandate

RFRA provides that the Government "shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability" unless the Government "demonstrates that application of the burden to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." 42 U.S.C. 2000bb–1(a) and (b). In *Hobby Lobby,* the Supreme Court had "little trouble concluding" that, in the absence of an accommodation or exemption, "the HHS contraceptive mandate 'substantially burden[s]' the exercise of religion. 42 U.S.C. 2000bb–1(a)." 134 S. Ct. at 2775. And although the Supreme Court did not resolve the RFRA claims presented in *Zubik* on their merits, it instructed the parties to consider alternative accommodations for the objecting plaintiffs, after the Government suggested that such alternatives might be possible.

Despite multiple rounds of rulemaking, however, the Departments have not assuaged the sincere religious objections to contraceptive coverage of numerous organizations, nor have we resolved the pending litigation. To the contrary, the Departments have been litigating RFRA challenges to the Mandate and related regulations for more than 5 years, and dozens of those challenges remain pending today. That litigation, and the related modifications to the accommodation, have consumed substantial governmental resources while creating uncertainty for objecting organizations, issuers, third party administrators, employees, and beneficiaries. Consistent with the President's Executive Order and the Government's desire to resolve the pending litigation and prevent future litigation from similar plaintiffs, the Departments have concluded that it is appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate.

These interim final rules (and the companion interim final rules published elsewhere in this **Federal Register**) are the result of that reexamination. The Departments acknowledge that coverage of contraception is an important and highly sensitive issue, implicating many different views, as reflected in the comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. After reconsidering the interests served by the Mandate in this particular context, the objections raised, and the applicable Federal law, the Departments have determined that an expanded exemption, rather than the existing accommodation, is the most appropriate administrative response to the religious objections raised by certain entities and organizations concerning the Mandate. The Departments have accordingly decided to revise the regulations channeling HRSA authority under section 2713(a)(4) of the PHS to provide an exemption from the Mandate to a broader range of entities and individuals that object to contraceptive coverage on religious grounds, while continuing to offer the existing accommodation as an optional alternative. The Departments have also decided to create a process by which a willing employer and issuer may allow an objecting individual employee to obtain health coverage without contraceptive coverage. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

In addition to relying on the text of section 2713(a)(4) of the PHS Act and the Departments' discretion to promulgate rules to carry out the provisions of the PHS Act, the Departments also draw on Congress' decision in the Affordable Care Act neither to specify that contraception must be covered nor to require inflexible across-the-board application of section 2713 of the PHS Act. The Departments further consider Congress' extensive history of protecting religious objections when certain matters in health care are specifically regulated—often specifically with respect to contraception, sterilization, abortion, and activities connected to abortion.

Notable among the many statutes (listed in footnote 1 in Section I-Background) that include protections for religious beliefs are, not only the Church Amendments, but also protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. (42 U.S.C. 1395w–22(j)(3)(B); 42 U.S.C. 1396u–2(b)(3)). In addition, Congress has protected individuals who object to prescribing or providing contraceptives contrary to their religious beliefs. Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31 (May 5, 2017). Congress likewise provided that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for

religious beliefs and moral convictions". *Id.* at Division C, Title VIII, Sec. 808. In light of the fact that Congress did not require HRSA to include contraception in Guidelines issued under section 2713 of the PHS Act, we consider it significant, in support of the implementation of those Guidelines by the expanded exemption in these interim final rules, that Congress' most recent statement on the prospect of Government mandated contraceptive coverage was to express the specific intent that a conscience clause be provided and that it should protect religious beliefs.

The Departments' authority to guide HRSA's discretion in determining the scope of any contraceptive coverage requirement under section 2713(a)(4) of the PHS Act includes the authority to provide exemptions and independently justifies this rulemaking. The Departments have also determined that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance violates their rights under RFRA.

A. Elements of RFRA

1. Substantial Burden

The Departments believe that agencies charged with administering a statute or associated regulations or guidance that imposes a substantial burden on the exercise of religion under RFRA have discretion in determining how to avoid the imposition of such burden. The Departments have previously contended that the Mandate does not impose a substantial burden on entities and individuals. With respect to the coverage Mandate itself, apart from the accommodation, and as applied to entities with religious objections, our argument was rejected in *Hobby Lobby*, which held that the Mandate imposes a substantial burden. (134 S. Ct. at 2775–79.) With respect to whether the Mandate imposes a substantial burden on entities that may choose the accommodation, but must choose between the accommodation, the Mandate, or penalties for noncompliance, a majority of Federal appeals courts have held that the accommodation does not impose a substantial burden on such entities (mostly religious nonprofit entities).

The Departments have reevaluated our position on this question, however, in light of all the arguments made in various cases, public comments that have been submitted, and the concerns discussed throughout these rules. We have concluded that requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA. We believe that the Court's analysis in *Hobby Lobby* extends, for the purposes of analyzing a substantial burden, to the burdens that an entity faces when it religiously opposes participating in the accommodation process or the straightforward Mandate, and is subject to penalties or disadvantages that apply in this context if it chooses neither. As the Eighth Circuit stated in *Sharpe Holdings*, "[i]n light of [nonprofit religious organizations'] sincerely held religious beliefs, we conclude that compelling their participation in the accommodation process by threat of severe monetary penalty is a substantial burden on their exercise of religion. . . . That they themselves do not have to arrange or pay for objectionable contraceptive coverage is not determinative of whether the required or forbidden act is or is not religiously offensive". (801 F.3d at 942.)

Our reconsideration of these issues has also led us to conclude, consistent with the rulings in favor of religious employee plaintiffs in *Wieland* and *March for Life* cited above, that the Mandate imposes a substantial burden on the religious beliefs of individual employees who oppose contraceptive coverage and would be able to obtain a plan that omits contraception from a willing employer or issuer (as applicable), but cannot obtain one solely because of the Mandate's prohibition on that employer and/or issuer providing them with such a plan.

Consistent with our conclusion earlier this year after the remand of cases in *Zubik* and our reviewing of comments submitted in response to the 2016 RFI, the Departments believe there is not a way to satisfy all religious objections by amending the accommodation. Accordingly, the Departments have decided it is necessary and appropriate to provide the expanded exemptions set forth herein.

2. Compelling Interest

Although the Departments previously took the position that the application of the Mandate to certain objecting employers was necessary to serve a compelling governmental interest, the Departments have now concluded, after reassessing the relevant interests and for the reasons stated below, that it does not. Under such circumstances, the Departments are required by law to alleviate the substantial burden created by the Mandate. Here, informed by the Departments' reassessment of the relevant interests, as well as by our desire to bring to a close the more than 5 years of litigation over RFRA challenges to the Mandate, the Departments have determined that the appropriate administrative response is to create a broader exemption, rather than simply adjusting the accommodation process.

RFRA requires the Government to respect religious beliefs under "the most demanding test known to constitutional law": Where the Government imposes a substantial burden on religious exercise, it must demonstrate a compelling governmental interest and show that the law or requirement is the least restrictive means of furthering that interest. *City of Boerne* v. *Flores*, 521 U.S. 507, 534 (1997). For an interest to be compelling, its rank must be of the "highest order". *Church of the Lukumi Babalu Aye, Inc.* v. *City of Hialeah*, 508 U.S. 520, 546 (1993); see also *Sherbert* v. *Verner*, 374 U.S. 398, 406–09 (1963); *Wisconsin* v. *Yoder*, 406 U.S. 205, 221–29 (1972). In applying RFRA, the Supreme Court has "looked beyond broadly formulated interests justifying the general applicability of government mandates and scrutinized the asserted harm of granting specific exemptions to particular religious claimants." *Gonzales* v. *O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 431 (2006). To justify a substantial burden on religious exercise under RFRA, the Government must show it has a compelling interest in applying the requirement to the "particular claimant[s] whose sincere exercise of religion is being substantially burdened." *Id.* at 430–31. Moreover, the Government must meet the "exceptionally demanding" least-restrictive-means standard. *Hobby Lobby*, 134 S. Ct. at 2780. Under that standard, the Government must establish that "it lacks other means of achieving its desired goal without imposing a substantial burden on the exercise of religion by the objecting parties." *Id.*

Upon further examination of the relevant provisions of the Affordable Care Act and the administrative record on which the Mandate was based, the Departments have concluded that the application of the Mandate to entities with sincerely held religious objections to it does not serve a compelling governmental interest. The Departments have reached that conclusion for multiple reasons, no one of which is dispositive.

First, Congress did not mandate that contraception be covered at all under the Affordable Care Act. Instead, Congress merely provided for coverage

of "such additional preventive care and screenings" for women "provided for in comprehensive guidelines supported by [HRSA]." Congress, thus, left the identification of any additional required preventive services for women to administrative discretion. The fact that Congress granted the Departments the authority to promulgate all rules appropriate and necessary for the administration of the relevant provisions of the Code, ERISA, and the PHS Act, including by channeling the discretion Congress afforded to HRSA to decide whether to require contraceptive coverage, indicates that the Departments' judgment should carry particular weight in considering the relative importance of the Government's interest in applying the Mandate to the narrow population of entities exempted in these rules.

Second, while Congress specified that many health insurance requirements added by the Affordable Care Act—including provisions adjacent to section 2713 of the PHS Act—were so important that they needed to be applied to all health plans immediately, the preventive services requirement in section 2713 of the PHS Act was not made applicable to "grandfathered plans." That feature of the Affordable Care Act is significant: As cited above, seven years after the Affordable Care Act's enactment, approximately 25.5 million people are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act. We do not suggest that a requirement that is inapplicable to grandfathered plans or otherwise subject to exceptions could never qualify as a serving a compelling interest under RFRA. For example, "[e]ven a compelling interest may be outweighed in some circumstances by another even weightier consideration." *Hobby Lobby,* 134 S. Ct. at 2780. But Congress' decision not to apply section 2713 of the PHS Act to grandfathered plans, while deeming other requirements closely associated in the same statute as sufficiently important to impose immediately, is relevant to our assessment of the importance of the Government interests served by the Mandate. As the Departments observed in 2010, those immediately applicable requirements were "particularly significant." (75 FR 34540). Congress' decision to leave section 2713 out of that category informs the Departments' assessment of the weight of the Government's interest in applying the Guidelines issued pursuant to section 2713 of the PHS Act to religious objectors.

Third, various entities that brought legal challenges to the Mandate (including some of the largest employers) have been willing to provide coverage of some, though not all, contraceptives. For example, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of 14 of 18 FDA-approved women's contraceptive and sterilization methods. (134 S. Ct. at 2766.) With respect to organizations and entities holding those beliefs, the fact that they are willing to provide coverage for various contraceptive methods significantly detracts from the government interest in requiring that they provide coverage for other contraceptive methods to which they object.

Fourth, the case for a compelling interest is undermined by the existing accommodation process, and how it applies to certain similarly situated entities based on whether or not they participate in certain self-insured group health plans, known as church plans, under applicable law. The Departments previously exempted eligible organizations from the contraceptive coverage requirement, and created an accommodation under which those organizations bore no obligation to provide for such coverage after submitting a self-certification or notice. Where a non-exempt religious organization uses an insured group health plan instead of a self-insured church plan, the health insurance issuer would be obliged to provide contraceptive coverage or payments to the plan's participants under the accommodation. Even in a self-insured church plan context, the preventive services requirement in section 2713(a)(4) of the PHS Act applies to the plan, and through the Code, to the religious organization that sponsors the plan. But under the accommodation, once a self-insured church plan files a self-certification or notice, the accommodation relieves it of any further obligation with respect to contraceptive services coverage. Having done so, the accommodation process would normally transfer the obligation to provide or arrange for contraceptive coverage to a self-insured plan's third party administrator (TPA). But the Departments lack authority to compel church plan TPAs to provide contraceptive coverage or levy fines against those TPAs for failing to provide it. This is because church plans are exempt from ERISA pursuant to section 4(b)(2) of ERISA. Section 2761(a) of the PHS Act provides that States may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but not as they pertain to church plans that do not provide coverage through a policy issued by a health insurance issuer. The combined result of PHS Act section 2713's authority to remove contraceptive coverage obligations from self-insured church plans, and HHS's and DOL's lack of authority under the PHS Act or ERISA to require TPAs to become administrators of those plans to provide such coverage, has led to significant incongruity in the requirement to provide contraceptive coverage among nonprofit organizations with religious objections to the coverage.

More specifically, issuers and third party administrators for some, but not all, religious nonprofit organizations are subject to enforcement for failure to provide contraceptive coverage under the accommodation, depending on whether they participate in a self-insured church plan. Notably, many of those nonprofit organizations are not houses of worship or integrated auxiliaries. Under section 3(33)(C)(iv) of ERISA, many organizations in self-insured church plans need not be churches, but can merely "share[] common religious bonds and convictions with [a] church or convention or association of churches". The effect is that many similar religious organizations are being treated very differently with respect to their employees receiving contraceptive coverage—depending on whether the organization is part of a church plan—even though the Departments claimed a compelling interest to deny exemptions to all such organizations. In this context, the fact that the Mandate and the Departments' application thereof "leaves appreciable damage to [their] supposedly vital interest unprohibited" is strong evidence that the Mandate "cannot be regarded as protecting an interest 'of the highest order.'" *Lukumi,* 508 U.S. at 520 (citation and quotation marks omitted).

Fifth, the Departments' previous assertion that the exemption for houses of worship was offered to respect a certain sphere of church autonomy (80 FR 41325) does not adequately explain some of the disparate results of the existing rules. And the desire to respect church autonomy is not grounds to prevent the Departments from expanding the exemption to other religious entities. The Departments previously treated religious organizations that operate in a similar fashion very differently for the purposes of the Mandate. For example, the Departments exempted houses of worship and integrated auxiliaries that may conduct activities, such as the

operating of schools, that are also conducted by non-exempt religious nonprofit organizations. Likewise, among religious nonprofit groups that were not exempt as houses of worship or integrated auxiliaries, many operate their religious activities similarly even if they differ in whether they participate in self-insured church plans. As another example, two religious colleges might have the same level of religiosity and commitment to defined ideals, but one might identify with a specific large denomination and choose to be in a self-insured church plan offered by that denomination, while another might not be so associated or might not have as ready access to a church plan and so might offer its employees a fully insured health plan. Under the accommodation, employees of the college using a fully insured plan (or a self-insured plan that is not a church plan) would receive coverage of contraceptive services without cost sharing, while employees of the college participating in the self-insured church plan would not receive the coverage where that plan required its third party administrator to not offer the coverage.

As the Supreme Court recently confirmed, a self-insured church plan exempt from ERISA through ERISA 3(33) can include a plan that is not actually established or maintained by a church or by a convention or association of churches, but is maintained by "an organization . . . the principal purpose or function of which is the administration or funding of a plan or program for the provision of retirement benefits or welfare benefits, or both, for the employees of a church or a convention or association of churches, if such organization is controlled by or associated with a church or a convention or association of churches" (a so-called "principal-purpose organization"). See *Advocate Health Care Network* v. *Stapleton*, 137 S. Ct. 1652, 1656–57 (U.S. June 5, 2017); ERISA 3(33)(C). While the Departments take no view on the status of these particular plans, the Departments acknowledge that the church plan exemption not only includes some non-houses-of-worship as organizations whose employees can be covered by the plan, but also, in certain circumstances, may include plans that are not themselves established and maintained by houses of worship. Yet, such entities and plans—if they file a self-certification or notice through the existing accommodation—are relieved of obligations under the contraceptive Mandate and their third party administrators are not subject to a requirement that they provide contraceptive coverage to their plan participants and beneficiaries.

After considering the differential treatment of various religious nonprofit organizations under the previous accommodation, the Departments conclude that it is appropriate to expand the exemption to other religious nonprofit organizations with sincerely held religious beliefs opposed to contraceptive coverage. We also conclude that it is not appropriate to limit the scope of a religious exemption by relying upon a small minority of State laws that contain narrow exemptions that focus on houses of worship and integrated auxiliaries. (76 FR 46623.)

Sixth, the Government's interest in ensuring contraceptive coverage for employees of particular objecting employers is undermined by the characteristics of many of those employers, especially nonprofit employers. The plaintiffs challenging the existing accommodation include, among other organizations, religious colleges and universities, and religious orders that provide health care or other charitable services. Based in part on our experience litigating against such organizations, the Departments now disagree with our previous assertion that "[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection." [18] (78 FR 39874.) Although empirical data was not required to reach our previous conclusion, we note that the conclusion was not supported by any specific data or other source, but instead was intended to be a reasonable assumption. Nevertheless, in the litigation and in numerous public comments submitted throughout the regulatory processes described above, many religious nonprofit organizations have indicated that they possess deep religious commitments even if they are not houses of worship or their integrated auxiliaries. Some of the religious nonprofit groups challenging the accommodation claim that their employees are required to adhere to a statement of faith which includes the entities' views on certain contraceptive items.[19] The Departments recognize, of course, that not all of the plaintiffs challenging the accommodation require all of their employees (or covered students) to share their religious objections to contraceptives. At the same time, it has become apparent from public comments and from court filings in dozens of cases—encompassing hundreds of organizations—that many religious nonprofit organizations express their beliefs publicly and hold themselves out as organizations for whom their religious beliefs are vitally important. Employees of such organizations, even if not required to sign a statement of faith, often have access to, and knowledge of, the views of their employers on contraceptive coverage, whether through the organization's published mission statement or statement of beliefs, through employee benefits disclosures and other communications with employees and prospective employees, or through publicly filed lawsuits objecting to providing such coverage and attendant media coverage. In many cases, the employees of religious organizations will have chosen to work for those organizations with an understanding—explicit or implicit—that they were being employed to advance the organization's goals and to be respectful of the organization's beliefs even if they do not share all of those beliefs. Religious nonprofit organizations that engage in expressive activity generally have a First Amendment right of expressive association and religious free exercise to choose to hire persons (or, in the case of students, to admit them) based on whether they share, or at least will be respectful of, their beliefs.[20]

Given the sincerely held religious beliefs of many religious organizations, imposing the contraceptive-coverage requirement on those that object based on such beliefs might undermine the Government's broader interests in ensuring health coverage by causing the entities to stop providing health coverage. For example, because the Affordable Care Act does not require

[18] In changing its position, an agency "need not demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

[19] See, for example, *Geneva College* v. *Sebelius*, 929 F. Supp. 2d 402, 411 (W.D. Pa. 2013); *Grace Schools* v. *Sebelius*, 988 F. Supp. 2d 935, 943 (N.D. Ind. 2013); Comments of the Council for Christian Colleges & Universities, re: CMS–9968–P (filed Apr. 8, 2013) ("On behalf of [] 172 higher education institutions . . . a requirement for membership in the CCCU is that full-time administrators and faculty at our institutions share the Christian faith of the institution.").

[20] Notably, "the First Amendment simply does not require that every member of a group agree on every issue in order for the group's policy to be 'expressive association.'" *Boy Scouts of America* v. *Dale*, 530 U.S. 640, 655 (2000).

institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or be subject to the accommodation with respect to such populations.[21]

Seventh, we now believe the administrative record on which the Mandate rests is insufficient to meet the high threshold to establish a compelling governmental interest in ensuring that women covered by plans of objecting organizations receive cost-free contraceptive coverage through those plans. To begin, in support of the IOM's recommendations, which HRSA adopted, the IOM identified several studies showing a preventive services gap because women require more preventive care than men. (IOM 2011 at 19–21). Those studies did not identify contraceptives or sterilization as composing a specific portion of that gap, and the IOM did not consider or establish in the report whether any cost associated with that gap remains after all other women's preventive services are covered without cost-sharing. *Id.* Even without knowing what the empirical data would show about that gap, the coverage of the other women's preventive services required under both the HRSA Guidelines and throughout section 2713(a) of the PHS Act—including annual well-woman visits and a variety of tests, screenings, and counseling services—serves at a minimum to diminish the cost gap identified by IOM for women whose employers decline to cover some or all contraceptives on religious grounds.[22]

Moreover, there are multiple Federal, State, and local programs that provide free or subsidized contraceptives for low-income women. Such Federal programs include, among others, Medicaid (with a 90 percent Federal match for family planning services), Title X, community health center grants, and Temporary Assistance for Needy Families. According to the Guttmacher Institute, government-subsidized family planning services are provided at 8,409 health centers overall.[23] The Title X program, for example, administered by the HHS Office of Population Affairs (OPA), provides a wide variety of voluntary family planning information and services for clients based on their ability to pay, through a network that includes nearly 4,000 family planning centers. *http://www.hhs.gov/opa/title-x-family-planning/* Individuals with family incomes at or below the HHS poverty guideline (for 2017, $24,600 for a family of four in the 48 contiguous States and the District of Columbia) receive services at no charge unless a third party (governmental or private) is authorized or obligated to pay for these services. Individuals with incomes in excess of 100 percent up to 250 percent of the poverty guideline are charged for services using a sliding fee scale based on family size and income. Unemancipated minors seeking confidential services are assessed fees based on their own income level rather than their family's income. The availability of such programs to serve the most at-risk women (as defined in the IOM report) diminishes the Government's interest in applying the Mandate to objecting employers. Many forms of contraception are available for around $50 per month, including long-acting methods such as the birth control shot and intrauterine devices (IUDs).[24] Other, more permanent forms of contraception like implantables bear a higher one-time cost, but when calculated over the duration of use, cost a similar amount.[25] Various State programs supplement the Federal programs referenced above, and 28 States have their own mandates of contraceptive coverage as a matter of State law. This existing inter-governmental structure for obtaining contraceptives significantly diminishes the Government's interest in applying the Mandate to employers over their sincerely held religious objections.

The record also does not reflect that the Mandate is tailored to the women most likely to experience unintended pregnancy, identified by the 2011 IOM report as "women who are aged 18 to 24 years and unmarried, who have a low income, who are not high school graduates, and who are members of a racial or ethnic minority". (IOM 2011 at 102). For example, with respect to religiously objecting organizations, the Mandate applies in employer-based group health plans and student insurance at private colleges and universities. It is not clear that applying the Mandate among those objecting entities is a narrowly tailored way to benefit the most at-risk population. The entities appear to encompass some such women, but also appear to omit many of them and to include a significantly larger cross-section of women as employees or plan participants. At the same time, the Mandate as applied to objecting employers appears to encompass a relatively small percentage of the number of women impacted by the Mandate overall, since most employers do not appear to have conscientious objections to the Mandate.[26] The Guttmacher Institute, on which the IOM relied, further reported that 89 percent of women who are at risk of unintended pregnancy and are living at 0 through 149 percent of the poverty line are already using contraceptives, as are 92 percent of those with incomes of 300 percent or more of the Federal poverty level.[27]

The rates of—and reasons for—unintended pregnancy are notoriously difficult to measure.[28] In particular, association and causality can be hard to disentangle, and the studies referred to by the 2011 IOM Report speak more to association than causality. For example, IOM 2011 references Boonstra, et al.

[21] See, for example, Manya Brachear Pashman, "Wheaton College ends coverage amid fight against birth control mandate," Chicago Tribune (July 29, 2015); Laura Bassett, "Franciscan University Drops Entire Student Health Insurance Plan Over Birth Control Mandate," HuffPost (May 15, 2012).

[22] The Departments are not aware of any objectors to the contraceptive Mandate that are unwilling to cover any of the other preventive services without cost sharing as required by PHS Act section 2713.

[23] "Facts on Publicly Funded Contraceptive Services in the United States," March 2016.

[24] See, for example, Caroline Cunningham, "How Much Will Your Birth Control Cost Once the Affordable Care Act Is Repealed?" *Washingtonian* (Jan. 17, 2017), available at *https://www.washingtonian.com/2017/01/17/how-much-will-your-birth-control-cost-once-the-affordable-care-act-is-repealed/*; also, see *https://www.plannedparenthood.org/learn/birth-control.*

[25] *Id.*

[26] Prior to the implementation of the Affordable Care Act approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2010 Annual Survey" at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf.* It is not clear whether the minority of employers who did not cover contraception refrained from doing so for conscientious reasons or for other reasons. Estimates of the number of women who might be impacted by the exemptions offered in these rules, as compared to the total number of women who will likely continue to receive contraceptive coverage, is discussed in more detail below.

[27] "Contraceptive Use in the United States," September 2016.

[28] The IOM 2011 Report reflected this when it cited the IOM's own 1995 report on unintended pregnancy, "The Best Intentions" (IOM 1995). IOM 1995 identifies various methodological difficulties in demonstrating the interest in reducing unintended pregnancies by means of a coverage mandate in employer plans. These include: The ambiguity of intent as an evidence-based measure (does it refer to mistimed pregnancy or unwanted pregnancy, and do studies make that distinction?); "the problem of determining parental attitudes at conception" and inaccurate methods often used for that assessment, such as "to use the request for an abortion as a marker"; and the overarching problem of "association versus causality," that is, whether intent causes certain negative outcomes or is merely correlated with them. IOM 1995 at 64–66. See also IOM 1995 at 222 ("the largest public sector funding efforts, Title X and Medicaid, have not been well evaluated in terms of their net effectiveness, including their precise impact on unintended pregnancy").

(2006), as finding that, "as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined," [29] and Santelli and Melnikas as finding that "increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are associated with lower rates of contraceptive use". IOM 2011 at 105.[30] In this respect, the report does not show that access to contraception causes decreased incidents of unintended pregnancy, because both of the assertions rely on association rather than causation, and they associate reduction in unintended pregnancy with increased use of contraception, not merely with increased access to such contraceptives.

Similarly, in a study involving over 8,000 women between 2012 and 2015, conducted to determine whether contraceptive coverage under the Mandate changed contraceptive use patterns, the Guttmacher Institute concluded that "[w]e observed no changes in contraceptive use patterns among sexually active women." [31] With respect to teens, the Santelli and Melnikas study cited by IOM 2011 observes that, between 1960 and 1990, as contraceptive use increased, teen sexual activity outside of marriage likewise increased (although the study does not assert a causal relationship).[32] Another study, which proposed an economic model for the decision to engage in sexual activity, stated that "[p]rograms that increase access to contraception are found to decrease teen pregnancies in the short run but increase teen pregnancies in the long run." [33] Regarding emergency contraception in particular, "[i]ncreased access to emergency contraceptive pills enhances use but has not been shown to reduce unintended pregnancy rates."[34] In the longer term—from 1972 through 2002—while the percentage of sexually experienced women who had ever used some form of contraception rose to 98 percent,[35] unintended pregnancy rates in the Unites States rose from 35.4 percent[36] to 49 percent."[37] The Departments note these and other studies[38] to observe the complexity and uncertainty in the relationship between contraceptive access, contraceptive use, and unintended pregnancy.

Contraception's association with positive health effects might also be partially offset by an association with negative health effects. In 2013 the National Institutes of Health indicated, in funding opportunity announcement for the development of new clinically useful female contraceptive products, that "hormonal contraceptives have the disadvantage of having many undesirable side effects[,] are associated with adverse events, and obese women are at higher risk for serious complications such as deep venous thrombosis." [39] In addition, IOM 2011 stated that "[l]ong-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases (PRB, 1998). The Agency for Healthcare Research and Quality (AHRQ) is currently undertaking a systematic evidence review to evaluate the effectiveness of oral contraceptives as primary prevention for ovarian cancer (AHRQ, 2011)." (IOM 2011 at 107). However, after IOM 2011 made this statement, AHRQ (a component of HHS) completed its systematic evidence review.[40] Based on its review, AHRQ stated that: "[o]varian cancer incidence was significantly reduced in OC [oral contraceptive] users"; "[b]reast cancer incidence was slightly but significantly increased in OC users"; "[t]he risk of cervical cancer was significantly increased in women with persistent human papillomavirus infection who used OCs, but heterogeneity prevented a formal meta-analysis"; "[i]ncidences of both colorectal cancer [] and endometrial cancer [] were significantly reduced by OC use"; "[t]he risk of vascular events was increased in current OC users compared with nonusers, although the increase in myocardial infarction was not statistically significant"; "[t]he overall strength of evidence for ovarian cancer prevention was moderate to low"; and "[t]he simulation model predicted that the combined increase in risk of breast and cervical cancers and vascular events was likely to be equivalent to or greater than the decreased risk in ovarian cancer."[41] Based on these findings, AHRQ concluded that "[t]here is insufficient evidence to recommend for or against the use of OCs solely for the primary prevention of ovarian cancer . . . . the harm/benefit ratio for ovarian cancer prevention alone is uncertain, particularly when the

[29] H. Boonstra, et al., "Abortion in Women's Lives" at 18, *Guttmacher Inst.* (2006).

[30] Citing John S. Santelli & Andrea J. Melnikas, "Teen Fertility in Transition: Recent and Historic Trends in the United States," 31 *Ann. Rev. Pub. Health* 371 (2010).

[31] Bearak, J.M. and Jones, R.K., "Did Contraceptive Use Patterns Change after the Affordable Care Act? A Descriptive Analysis," 27 *Women's Health Issues* 316 (Guttmacher Inst. May–June 2017), available at *http://www.whijournal.com/article/S1049-3867(17)30029-4/fulltext.*

[32] 31 *Ann. Rev. Pub. Health* at 375–76.

[33] Peter Arcidiacono, et al., "Habit Persistence and Teen Sex: Could Increased Access to Contraception Have Unintended Consequences for Teen Pregnancies?" (2005), *available at http://public.econ.duke.edu/~psarcidi/teensex.pdf.*

[34] G. Raymond et al., "Population effect of increased access to emergency contraceptive pills: a systematic review." 109 Obstet. Gynecol. 181 (2007).

[35] William D. Mosher & Jo Jones, U.S. Dep't of HHS, CDC, National Center for Health Statistics, "Use of Contraception in the United States: 1982–2008" at 5 fig. 1, 23 *Vital and Health Statistics* 29 (Aug. 2010), available at *https://www.cdc.gov/nchs/data/series/sr_23/sr23_029.pdf.*

[36] Helen M. Alvaré, "No Compelling Interest: The 'Birth Control' Mandate and Religious Freedom," 58 *Vill. L. Rev.* 379, 404–05 & n.128 (2013), available at *http://digitalcommons.law.villanova.edu/vlr/vol58/iss3/2* (quoting Christopher Tietze, "Unintended Pregnancies in the United States, 1970–1972," 11 *Fam. Plan. Persp.* 186, 186 n.* (1979) ("in 1972, 35.4 percent percent of all U.S. pregnancies were 'unwanted' or 'wanted later'")).

[37] *Id.* (citing Lawrence B. Finer & Stanley K. Henshaw, "Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001" 38 *Persp. on Sexual Reprod. Health* 90 (2006) ("In 2001, 49 percent of pregnancies in the United States were unintended")).

[38] See, for example, J.L Dueñas, et al., "Trends in the Use of Contraceptive Methods and Voluntary Interruption of Pregnancy in the Spanish Population during 1997–2007," 83 *Contraception* 82 (2011) (as use of contraceptives increased from 49 percent to 80 percent, the elective abortion rate more than doubled); D. Paton, "The economics of family planning and underage conceptions," 21 *J. Health Econ.* 207 (2002) (data from the UK confirms an economic model which suggests improved family planning access for females under 16 increases underage sexual activity and has an ambiguous impact on underage conception rates); T. Raine et al., "Emergency contraception: advance provision in a young, high-risk clinic population," 96 *Obstet. Gynecol.* 1 (2000) (providing advance provision of emergency contraception at family planning clinics to women aged 16–24 was associated with the usage of less effective and less consistently used contraception by other methods); M. Belzer et al., "Advance supply of emergency contraception: a randomized trial in adolescent mothers," 18 *J. Pediatr. Adolesc. Gynecol.* 347 (2005) (advance provision of emergency contraception to mothers aged 13–20 was associated with increased unprotected sex at the 12-month follow up).

[39] NIH, "Female Contraceptive Development Program (U01)" (Nov. 5, 2013), available at *https://grants.nih.gov/grants/guide/rfa-files/RFA-HD-14-024.html.* Thirty six percent of women in the United States are obese. *https://www.niddk.nih.gov/health-information/health-statistics/overweight-obesity.* Also see "Does birth control raise my risk for health problems?" and "What are the health risks for smokers who use birth control?" HHS Office on Women's Health, available at *https://www.womenshealth.gov/a-z-topics/birth-control-methods*; Skovlund, CW, "Association of Hormonal Contraception with Depression," 73 *JAMA Psychiatry* 1154 (Nov. 1, 2016), available at *https://www.ncbi.nlm.nih.gov/pubmed/27680324.*

[40] Havrilesky, L.J, et al., "Oral Contraceptive User for the Primary Prevention of Ovarian Cancer," Agency for Healthcare Research and Quality, Report No.: 13–E002–EF (June 2013), available at *https://archive.ahrq.gov/research/findings/evidence-based-reports/ocusetp.html.*

[41] *Id.*

potential quality-of-life impact of breast cancer and vascular events are considered."[42]

In addition, in relation to several studies cited above, imposing a coverage Mandate on objecting entities whose plans cover many enrollee families who may share objections to contraception could, among some populations, affect risky sexual behavior in a negative way. For example, it may not be a narrowly tailored way to advance the Government interests identified here to mandate contraceptive access to teenagers and young adults who are not already sexually active and at significant risk of unintended pregnancy.[43]

Finally, evidence from studies that post-date the Mandate is not inconsistent with the observations the Departments make here. In 2016, HRSA awarded a 5-year cooperative agreement to the American College of Obstetricians and Gynecologists to develop recommendations for updated Women's Preventive Services Guidelines. The awardee formed an expert panel called the Women's Preventive Services Initiative that issued a report (the WPSI report).[44] After observing that "[p]rivate companies are increasingly challenging the contraception provisions in the Affordable Care Act," the WPSI report cited studies through 2013 stating that application of HRSA Guidelines had applied preventive services coverage to 55.6 million women and had led to a 70 percent decrease in out-of-pocket expenses for contraceptive services among commercially insured women. *Id.* at 57–58. The WPSI report relied on a 2015 report of the HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), "The Affordable Care Act Is Improving Access to Preventive Services for Millions of Americans," which estimated that persons who have private insurance coverage of preventive services without cost sharing includes 55.6 million women.[45]

As discussed above and based on the Departments' knowledge of litigation challenging the Mandate, during the time ASPE estimated the scope of preventive services coverage (2011–2013), houses of worship and integrated auxiliaries were exempt from the Mandate, other objecting religious nonprofit organizations were protected by the temporary safe harbor, and hundreds of accommodated self-insured church plan entities were not subject to enforcement of the Mandate through their third party administrators. In addition, dozens of for-profit entities that had filed lawsuits challenging the Mandate were protected by court orders pending the Supreme Court's resolution of *Hobby Lobby* in June 2014. It would therefore appear that the benefits recorded by the report occurred even though most objecting entities were not in compliance.[46] Additional data indicates that, in 28 States where contraceptive coverage mandates have been imposed statewide, those mandates have not necessarily lowered rates of unintended pregnancy (or abortion) overall.[47]

The Departments need not take a position on these empirical questions. Our review is sufficient to lead us to conclude that significantly more uncertainty and ambiguity exists in the record than the Departments previously acknowledged when we declined to extend the exemption to certain objecting organizations and individuals as set forth herein, and that no compelling interest exists to counsel against us extending the exemption.

During public comment periods, some commenters noted that some drugs included in the preventive services contraceptive Mandate can also be useful for treating certain existing health conditions. The IOM similarly stated that "the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain." IOM 2011 at 107. Consequently, some commenters suggested that religious objections to the Mandate should not be permitted in cases where such methods are used to treat such conditions, even if those methods can also be used for contraceptive purposes. Section 2713(a)(4) of the PHS Act does not, however, apply to non-preventive care provided solely for treatment of an existing condition. It applies only to "such additional preventive care and screenings . . . as provided for" by HRSA (Section 2713(a)(4) of the PHS Act). HRSA's Guidelines implementing this section state repeatedly that they apply to "preventive" services or care, and with respect to the coverage of contraception specifically, they declare that the methods covered are "contraceptive" methods as a "Type of Preventive Service," and that they are to be covered only "[a]s prescribed" by a physician or other health care provider. *https://www.hrsa.gov/womensguidelines/* The contraceptive coverage requirement in the Guidelines also only applies for "women with reproductive capacity." *https://www.hrsa.gov/womensguidelines/*; (80 FR 40318). Therefore, the Guidelines' inclusion of contraceptive services requires coverage of contraceptive methods as a type of preventive service only when a drug that the FDA has approved for contraceptive use is prescribed in whole or in part for such use. The Guidelines and section 2713(a)(4) of the PHS Act do not require coverage of such drugs where they are prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition.[48] As discussed above, the last

[42] *Id.* Also, see Kelli Miller, "Birth Control & Cancer: Which Methods Raise, Lower Risk," *The Am. Cancer Society*, (Jan. 21, 2016), available at *http://www.cancer.org/cancer/news/features/birth-control-cancer-which-methods-raise-lower-risk.*

[43] For further discussion, see Alvaré, 58 *Vill. L. Rev.* at 400–02 (discussing the Santelli & Melnikas study and the Arcidiacono study cited above, and other research that considers the extent to which reduction in teen pregnancy is attributable to sexual risk avoidance rather than to contraception access).

[44] "WPSI 2016 Recommendations: Evidence Summaries and Appendices," at 54–64, *available at https://www.womenspreventivehealth.org/wp-content/uploads/2016/12/Evidence-Summaries-and-Appendices.pdf.*

[45] Available at *https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans*; also, see Abridged Report, available at *https://www.womenspreventivehealth.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf.*

[46] In addition, as in IOM 2011, the WPSI report bases its evidentiary conclusions relating to contraceptive coverage, use, unintended pregnancy, and health benefits, on conclusions that the phenomena are "associated" with the intended outcomes, without showing there is a causal relationship. For example, the WPSI report states that "[c]ontraceptive counseling in primary care may increase the uptake of hormonal methods and [long-acting reversible contraceptives], although data on structured counseling in specialized reproductive health settings demonstrated no such effect." *Id.* at 63. The WPSI report also acknowledges that a large-scale study evaluating the effects of providing no-cost contraception had "no randomization or control group." *Id.* at 63.

The WPSI report also identifies the at-risk population as young, low-income, and/or minority women: "[u]nintended pregnancies disproportionately occur in women age 18 to 24 years, especially among those with low incomes or from racial/ethnic minorities." *Id.* at 58. The WPSI report acknowledges that many in this population are already served by Title X programs, which provide family planning services to "approximately 1 million teens each year." *Id.* at 58. The WPSI report observes that between 2008 and 2011—before the contraceptive coverage requirement was implemented—unintended pregnancy decreased to the lowest rate in 30 years. *Id.* at 58. The WPSI report does not address how to balance contraceptive coverage interests with religious objections, nor does it specify the extent to which applying the Mandate among commercially insured at objecting entities serves to deliver contraceptive coverage to women most at risk of unintended pregnancy.

[47] See Michael J. New, "Analyzing the Impact of State Level Contraception Mandates on Public Health Outcomes," 13 *Ave Maria L. Rev.* 345 (2015), available at *http://avemarialaw-law-review.avemarialaw.edu/Content/articles/vXIII.i2.new.final.0809.pdf.*

[48] The Departments previously cited the IOM's listing of existing conditions that contraceptive drugs can be used to treat (menstrual disorders, acne, and pelvic pain), and said of those uses that "there are demonstrated preventive health benefits

Continued

Administration decided to exempt houses of worship and their integrated auxiliaries from the Mandate, and to relieve hundreds of religious nonprofit organizations of their obligations under the Mandate and not further require contraceptive coverage to their employees. In several of the lawsuits challenging the Mandate, some religious plaintiffs stated that they do not object and are willing to cover drugs prescribed for the treatment of an existing condition and not for contraceptive purposes—even if those drugs are also approved by the FDA for contraceptive uses. Therefore, the Departments conclude that the fact that some drugs that are approved for preventive contraceptive purposes can also be used for exclusively non-preventive purposes to treat existing conditions is not a sufficient reason to refrain from expanding the exemption to the Mandate.

An additional consideration supporting the Departments' present view is that alternative approaches can further the interests the Departments previously identified behind the Mandate. As noted above, the Government already engages in dozens of programs that subsidize contraception for the low-income women identified by the IOM as the most at risk for unintended pregnancy. The Departments have also acknowledged in legal briefing that contraception access can be provided through means other than coverage offered by religious objectors, for example, through "a family member's employer," "an Exchange," or "another government program." [49]

Many employer plan sponsors, institutions of education arranging student health coverage, and individuals enrolled in plans where their employers or issuers (as applicable) are willing to offer them a religiously acceptable plan, hold sincerely held religious beliefs against (respectively) providing, arranging, or participating in plans that comply with the Mandate either by providing contraceptive coverage or by using the accommodation. Because we have concluded that requiring such compliance through the Mandate or accommodation has constituted a substantial burden on the religious exercise of many such entities or individuals, and because we conclude requiring such compliance did not serve a compelling interest and was not the least restrictive means of serving a compelling interest, we now believe that requiring such compliance led to the violation of RFRA in many instances. We recognize that this is a change of position on this issue, and we make that change based on all the matters discussed in this preamble.

B. Discretion To Provide Religious Exemptions

Even if RFRA does not compel the religious exemptions provided in these interim final rules, the Departments believe they are the most appropriate administrative response to the religious objections that have been raised. RFRA identifies certain circumstance under which government must accommodate religious exercise-when a government action imposes a substantial burden on the religious exercise of an adherent and imposition of that burden is not the least restrictive means of achieving a compelling government interest. RFRA does not, however, prescribe the accommodation that the government must adopt. Rather, agencies have discretion to fashion an appropriate and administrable response to respect religious liberty interests implicated by their own regulations. We know from *Hobby Lobby* that, in the absence of any accommodation, the contraceptive-coverage requirement imposes a substantial burden on certain objecting employers. We know from other lawsuits and public comments that many religious entities have objections to complying with the accommodation based on their sincerely held religious beliefs. Previously, the Departments attempted to develop an accommodation that would either alleviate the substantial burden imposed on religious exercise or satisfy RFRA's requirements for imposing that burden.

Now, however, the Departments have reassessed the relevant interests and determined that, even if exemptions are not required by RFRA, they would exercise their discretion to address the substantial burden identified in *Hobby Lobby* by expanding the exemptions from the Mandate instead of revising accommodations previously offered. In the Departments' view, a broader exemption is a more direct, effective means of satisfying all bona fide religious objectors. This view is informed by the fact that the Departments' previous attempt to develop an appropriate accommodation did not satisfy all objectors. That previous accommodation consumed Departmental resources not only through the regulatory process, but in persistent litigation and negotiations. Offering exemptions as described in these interim final rules is a more workable way to respond to the substantial burden identified in *Hobby Lobby* and bring years of litigation concerning the Mandate to a close.

C. General Scope of Expanded Religious Exemptions

1. Exemption and Accommodation for Religious Employers, Plan Sponsors, and Institutions of Higher Education

For all of these reasons, and as further explained below, the Departments now believe it is appropriate to modify the scope of the discretion afforded to HRSA in the July 2015 final regulations to direct HRSA to provide the expanded exemptions and change the accommodation to an optional process if HRSA continues to otherwise provide for contraceptive coverage in the Guidelines. As set forth below, the expanded exemption encompasses non-governmental plan sponsors that object based on sincerely held religious beliefs, and institutions of higher education in their arrangement of student health plans. The accommodation is also maintained as an optional process for exempt employers, and will provide contraceptive availability for persons covered by the plans of entities that use it (a legitimate program purpose).

The Departments believe this approach is sufficiently respectful of religious objections while still allowing the Government to advance other interests. Even with the expanded exemption, HRSA maintains the discretion to require contraceptive coverage for nearly all entities to which the Mandate previously applied (since most plan sponsors do not appear to possess the requisite religious objections), and to reconsider those interests in the future where no covered objection exists. Other Government subsidies of contraception are likewise not affected by this rule.

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from contraceptives relating to conditions other than pregnancy." 77 FR 8727 & n.7. This was not, however, an assertion that PHS Act section 2713(a)(4) or the Guidelines require coverage of "contraceptive" methods when prescribed for an exclusively *non*-contraceptive, *non*-preventive use. Instead it was an observation that such drugs—generally referred to as "contraceptives"—also have some alternate beneficial uses to treat existing conditions. For the purposes of these interim final rules, the Departments clarify here that our previous reference to the benefits of using contraceptive drugs exclusively for some non-contraceptive and non-preventive uses to treat existing conditions did not mean that the Guidelines require coverage of such uses, and consequently is not a reason to refrain from offering the expanded exemptions provided here. Where a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage. Where a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines.

[49] Brief for the Respondents at 65, *Zubik* v. *Burwell*, 136 S. Ct. 1557 (2016) (No. 14–1418).

2. Exemption for Objecting Individuals Covered by Willing Employers and Issuers

As noted above, some individuals have brought suit objecting to being covered under an insurance policy that includes coverage for contraceptives. See, for example, *Wieland* v. *HHS*, 196 F. Supp. 3d 1010 (E.D. Mo. 2016); *Soda* v. *McGettigan*, No. 15–cv–00898 (D. Md.). Just as the Departments have determined that the Government does not have a compelling interest in applying the Mandate to employers that object to contraceptive coverage on religious grounds, we have also concluded that the Government does not have a compelling interest in requiring individuals to be covered by policies that include contraceptive coverage when the individuals have sincerely held religious objections to that coverage. The Government does not have an interest in ensuring the provision of contraceptive coverage to individuals who do not wish to have such coverage. Especially relevant to this conclusion is the fact that the Departments have described their interests of health and gender equality as being advanced among women who "want" the coverage so as to prevent "unintended" pregnancy. (77 FR 8727).[50] No asserted interest is served by denying an exemption to individuals who object to it. No unintended pregnancies will be avoided or costs reduced by imposing the coverage on those individuals.

Although the Departments previously took the position that allowing individual religious exemptions would undermine the workability of the insurance system, the Departments now agree with those district courts that have concluded that an exemption that allows—but does not require—issuers and employers to omit contraceptives from coverage provided to objecting individuals does not undermine any compelling interest. See *Wieland*, 196 F. Supp. 3d at 1019–20; *March for Life*, 128 F. Supp. 3d at 132. The individual exemption will only apply where the employer and issuer (or, in the individual market, the issuer) are willing to offer a policy accommodating the objecting individual. As a result, the Departments consider it likely that where an individual exemption is invoked, it will impose no burdens on the insurance market because such burdens may be factored into the willingness of an employer or issuer to offer such coverage. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments' previous exemption for houses of worship and integrated auxiliaries, and our lack of authority to enforce the accommodation with respect to self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.[51] Furthermore, granting exemptions to individuals who do not wish to receive contraceptive coverage where the plan and, as applicable, issuer and plan sponsor are willing, does not undermine the Government's interest in ensuring the provision of such coverage to other individuals who wish to receive it. Nor do such exemptions undermine the operation of the many other programs subsidizing contraception. Rather, such exemptions serve the Government's interest in accommodating religious exercise. Accordingly, as further explained below, the Departments have provided an exemption to address the concerns of objecting individuals.

D. Effects on Third Parties of Exemptions

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 of the PHS Act requirements on grandfathered plans that cover millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have other avenues for obtaining contraception, including the various governmental programs discussed above. As the Government is under no constitutional obligation to fund contraception, *cf. Harris* v. *McRae*, 448 United States 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their religious beliefs. *Cf. Rust* v. *Sullivan*, 500 U.S. 173, 192–93 (1991) ("A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.").[52]

That conclusion is consistent with the Supreme Court's observation that RFRA may require exemptions even from laws requiring claimants "to confer benefits on third parties." *Hobby Lobby*, 134 S. Ct. at 2781 n.37. The burdens imposed on such third parties may be relevant to the RFRA analysis, but they cannot be dispositive. "Otherwise, for example, the Government could decide that all supermarkets must sell alcohol for the convenience of customers (and thereby exclude Muslims with religious objections from owning supermarkets), or it could decide that all restaurants must remain open on Saturdays to give employees an opportunity to earn tips (and thereby exclude Jews with religious objections from owning restaurants)." *Id.* Where, as here, contraceptives are readily accessible and, for many low income persons, are available at reduced cost or for free through various governmental programs, and contraceptive coverage may be available through State sources or family plans obtained through non-objecting employers, the Departments have determined that the expanded exemptions rather than accommodations are the appropriate response to the substantial burden that the Mandate has placed upon the religious exercise of many religious employers.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including prior interim final rules), public comments, and litigation throughout the Federal court system. The interim final rules seek to resolve this matter and the long-running litigation with respect to religious

[50] In this respect, the Government's interest in contraceptive coverage is different than its interest in persons receiving some other kinds of health coverage or coverage in general, which can lead to important benefits that are not necessarily conditional on the recipient's desire to use the coverage and the specific benefits that may result from their choice to use it.

[51] Also, see *Real Alternatives*, 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) ("Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the Affordable Care Act) would be unworkable, it has not satisfied strict scrutiny." (citation and internal quotation marks omitted)).

[52] *Cf. also Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011) ("a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either.").

objections by extending the exemption under the HRSA Guidelines to encompass entities, and individuals, with sincerely held religious beliefs objecting to contraceptive or sterilization coverage, and by making the accommodation process optional for eligible organizations.

The Departments acknowledge that the foregoing analysis represents a change from the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlie the Mandate. These changes in policy are within the Departments' authority. As the Supreme Court has acknowledged, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC* v. *Navarro,* 136 S. Ct. 2117, 2125 (2016). This "reasoned analysis" requirement does not demand that an agency "demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates". *United Student Aid Funds, Inc.* v. *King,* 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009)); also, see *New Edge Network, Inc.* v. *FCC,* 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").

Here, for all of the reasons discussed above, the Departments have determined that the Government's interest in the application of contraceptive coverage requirements in this specific context to the plans of certain entities and individuals does not outweigh the sincerely held religious objections of those entities and individuals based on the analyses set forth above. Thus, these interim final rules amend the Departments' July 2015 final regulations to expand the exemption to include additional entities and persons that object based on sincerely held religious beliefs. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no such objection exists, and to the extent that section 2713 of the PHS Act applies. These interim final rules also maintain the existence of an accommodation process, but consistent with our expansion of the exemption, we make the process optional for eligible organizations. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.[53]

A. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules modify the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) introductory text and (a)(1)(iv), so that they conform to the statutory text of section 2713 of the PHS Act.

B. Prefatory Language of the Exemption in 45 CFR 147.132

These interim final rules move the religious exemption from 45 CFR 147.131 to a new § 147.132 and expand it as follows. In the prefatory language of § 147.132, these interim final rules specify that not only are certain entities "exempt," but the Guidelines shall not support or provide for an imposition of the contraceptive coverage requirement to such entities. This is an acknowledgement that section 2713(a)(4) of the PHS Act requires women's preventive services coverage only "as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." To the extent the HRSA Guidelines do not provide for or support the application of such coverage to exempt entities, the Affordable Care Act does not require the coverage. Section 147.132 not only describes the exemption of certain entities and plans, but does so by specifying that the HRSA Guidelines do not provide for, or support the application of, such coverage to exempt entities and plans.

C. General Scope of Exemption for Objecting Entities

In the new 45 CFR 147.132 as created by these interim final rules, these rules expand the exemption that was previously located in § 147.131(a). With respect to employers that sponsor group health plans, the new language of § 147.132(a)(1) introductory text and (a)(1)(i) provides exemptions for employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held religious beliefs.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption created in § 147.132(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.132(a)(1) introductory text and (a)(1)(i), by specifying that "[a] group health plan and health insurance coverage provided in connection with a group health plan" is exempt "to the extent the plan sponsor objects as specified in paragraph (a)(2)," exempt the group health plans the sponsors of which object, and exempt their health insurance issuers from providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[54] Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage,

[53] See *https://www.hrsa.gov/womensguidelines/* and *https://www.hrsa.gov/womensguidelines2016/index.html.*

[54] See, for example, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. Also, see 45 CFR 147.200 (requiring disclosure of the "exceptions, reductions, and limitations of the coverage," including group health plans and group & individual issuers).

otherwise applicable ERISA disclosures must reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.132(a) apply "to the extent" of the objecting entities' sincerely held religious beliefs. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.132(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsor has no qualifying objection. The objection of a health insurance issuer in § 147.132(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

D. Exemption of Employers and Institutions of Higher Education

The scope of the exemption is expanded for non-governmental plan sponsors and certain entities that arrange health coverage under these interim final rules. The Departments have consistently taken the position that section 2713(a)(4) of the PHS Act grants HRSA authority to issue Guidelines that provide for and support exemptions from a contraceptive coverage requirement. Since the beginning of rulemaking concerning the Mandate, HRSA and the Departments have repeatedly exercised their discretion to create and modify various exemptions within the Guidelines.[55]

The Departments believe the approach of these interim final rules better aligns our implementation of section 2713(a)(4) of the PHS Act with Congress' intent in the Affordable Care Act and throughout other Federal health care laws. As discussed above, many Federal health care laws and regulations provide exemptions for objections based on religious beliefs, and RFRA applies to the Affordable Care Act. Expanding the exemption removes religious obstacles that entities and certain individuals may face when they otherwise wish to participate in the health care market. This advances the Affordable Care Acts goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate. These rules also leave in place many Federal programs that subsidize contraceptives for women who are most at risk of unintended pregnancy and who may have more limited access to contraceptives.[56] These interim final rules achieve greater uniformity and simplicity in the regulation of health insurance by expanding the exemptions to include entities that object to the Mandate based on their sincerely held religious beliefs.

The Departments further conclude that it would be inadequate to merely attempt to amend the accommodation process instead of expand the exemption. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way "seamless" to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. The Departments have engaged in an effort to attempt to identify an accommodation that would eliminate the plaintiffs' religious objections, including seeking public comment through an RFI, but we stated in January 2017 that we were unable to develop such an approach at that time.

1. Plan Sponsors Generally

The expanded exemptions in these interim final rules cover any kind of non-governmental employer plan sponsor with the requisite objections but, for the sake of clarity, they include an illustrative, non-exhaustive list of employers whose objections qualify the plans they sponsor for an exemption.

Under these interim final rules, the Departments do not limit the Guidelines exemption with reference to nonprofit status or to sections 6033(a)(3)(A)(i) or (iii) of the Code, as previous rules have done. A significant majority of States either impose no contraceptive coverage requirement or offer broader exemptions than the exemption contained in the July 2015 final regulations.[57] Although the practice of States is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor a statement about what the Federal Government may do consistent with RFRA or other limitations in federal law, such State practice can be informative as to the viability of broad protections for religious liberty. In this case, such practice supports the Departments' decision to expand the federal exemption, bringing the Federal Government's practice into greater alignment with the practices of the majority of the States.

2. Section 147.132(a)(1)(i)(A)

Despite not limiting the exemption to certain organizations referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, the exemption in these rules includes such organizations. Section 147.132(a)(1)(i)(A) specifies, as under the prior exemption, that the exemption covers "a group health plan established or maintained by . . . [a] church, the integrated auxiliary of a church, a convention or association of churches, or a religious order." In the preamble to rules setting forth the prior exemption at § 147.132(a), the Departments interpreted this same language used in those rules by declaring that "[t]he final regulations continue to provide that the availability of the exemption or accommodation be determined on an employer by employer basis, which the Departments continue to believe best balances the interests of religious employers and eligible organizations and those of employees and their dependents." (78 FR 39886). Therefore, under the prior exemption, if an employer participated in a house of worship's plan—perhaps because it was affiliated with a house of worship—but was not an integrated auxiliary or a house of worship itself, that employer was not considered to be covered by the

[55] "The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute." *Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863–64 (1984).

[56] See, for example, Family Planning grants in 42 U.S.C. 300, *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[57] See Guttmacher Institute, "Insurance Coverage of Contraceptives" available at *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives.*

exemption, even though it was, in the ordinary meaning of the text of the prior regulation, participating in a "plan established or maintained by a [house of worship]."

Under these interim final rules, however, the Departments intend that, when this regulation text exempts a plan "established or maintained by" a house of worship or integrated auxiliary, such exemption will no longer "be determined on an employer by employer basis," but will be determined on a plan basis—that is, by whether the plan is a "plan established or maintained by" a house of worship or integrated auxiliary. This interpretation better conforms to the text of the regulation setting forth the exemption—in both the prior regulation and in the text set forth in these interim final rules. It also offers appropriate respect to houses of worship and their integrated auxiliaries not only in their internal employment practices but in their choice of organizational form and/or in their activity of establishing or maintaining health plans for employees of associated employers that do not meet the threshold of being integrated auxiliaries. Moreover, under this interpretation, houses of worship would not be faced with the potential prospect of services to which they have a religious objection being covered for employees of an associated employer participating in a plan they have established and maintain.

The Departments do not believe there is a sufficient factual basis to exclude from this part of the exemption entities that are so closely associated with a house of worship or integrated auxiliary that they are permitted participation in its health plan, but are not themselves integrated auxiliaries. Additionally, this interpretation is not inconsistent with the operation of the accommodation under the prior rule, to the extent that, in practice and as discussed elsewhere herein, it does not force contraceptive coverage to be provided on behalf of the plan participants of many religious organizations in a self-insured church plan exempt from ERISA—which are exempt in part because the plans are established and maintained by a church. (Section 3(33)(A) of ERISA) In several lawsuits challenging the Mandate, the Departments took the position that some plans established and maintained by houses of worship, but that included entities that were not integrated auxiliaries, were church plans under section 3(33) of ERISA and, thus, the Government "has no authority to require the plaintiffs' TPAs to provide contraceptive coverage at this time." *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013). Therefore the Departments believe it is most appropriate to use a plan basis, not an employer by employer basis, to determine the scope of an exemption for a group health plan established or maintained by a house of worship or integrated auxiliary.

3. Section 147.132(a)(1)(i)(B)

Section 147.132(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of plan sponsors that are nonprofit organizations.

4. Section 147.132(a)(1)(i)(C)

Under § 147.132(a)(1)(i)(C), the rules extend the exemption to the plans of closely held for-profit entities. This is consistent with the Supreme Court's ruling in *Hobby Lobby,* which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the Departments' argument to the contrary. (134 S. Ct. 2768–75) Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.[58]

5. Section 147.132(a)(1)(i)(D)

Under § 147.132(a)(1)(i)(D), the rules extend the exemption to the plans of for-profit entities that are not closely held. The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. The Departments implicitly recognized the difficulty of providing an affirmative definition of closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely "substantially similar" to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. The exemptions in these interim final rules do not need to address this difficulty because they include both for-profit entities that are closely held and for-profit entities that are not closely held.[59] The mechanisms for determining whether a company has adopted and holds such principles or views is a matter of well-established State law with respect to corporate decision-making,[60] and the Departments expect that application of such laws would cabin the scope of this exemption.

In including entities in the exemption that are not closely held, these interim final rules provide for the possibility that some publicly traded entities may use the exemption. Even though the Supreme Court did not extend its holding in *Hobby Lobby* to publicly traded corporations (the matter could be resolved without deciding that question), the Court did instruct that RFRA applies to corporations because they are "persons" as that term is defined in 1 U.S.C. 1. Given that the definition under 1 U.S.C. 1 applies to any corporation, the Departments consider it appropriate to extend the exemption set forth in these interim final rules to for-profit corporations whether or not they are closely held. The Departments are generally aware that in a country as large as America comprised of a supermajority of religious persons, some publicly traded entities might claim a religious character for their company, or that the majority of shares (or voting shares) of some publicly traded companies might be controlled by a small group of religiously devout persons so as to set forth such a religious character.[61] The fact that such a company is religious does not mean that it will have an objection to contraceptive coverage, and there are many fewer publicly traded companies than there are closely held ones. But our experience with closely held companies is that some, albeit a small minority, do have religious objections to contraceptive coverage. Thus we consider it possible, though very unlikely, that a religious publicly

[58] See Jennifer Haberkorn, "Two years later, few Hobby Lobby copycats emerge," *Politico* (Oct. 11, 2016), available at *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627.*

[59] In the companion interim final rules published elsewhere in this **Federal Register**, the Departments provide an exemption on an interim final basis to closely held entities by using a negative definition: entities that do not have publicly traded ownership interests as defined by certain securities required to be registered under section 12 of the Securities Exchange Act of 1934. Although this is a more workable definition than set forth in our previous rules, we have determined that it is appropriate to offer the expanded religious exemptions to certain entities whether or not they have publicly traded ownership interests.

[60] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

[61] *See, e.g., Nasdaq.com,* "4 Publicly Traded Religious Companies if You're Looking to Invest in Faith" (Feb. 7, 2014), available at *http://www.nasdaq.com/article/4-publicly-traded-religious-companies-if-youre-looking-to-invest-in-faith-cm324665.*

traded company might have objections to contraceptive coverage. At the same time, we are not aware of any publicly traded entities that challenged the Mandate specifically either publicly or in court. The Departments agree with the Supreme Court that it is improbable that many publicly traded companies with numerous "unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs" and thereby qualify for the exemption. (134 S. Ct. at 2774)

6. Section 147.132(a)(1)(i)(E)

Under § 147.132(a)(1)(i)(E), the rules extend the exemption to the plans of any other non-governmental employer. The plans of governmental employers are not covered by the plan sponsor exemption of § 147.132(a)(1)(i). The Departments are not aware of reasons why it would be appropriate or necessary to offer religious exemptions to governmental employer plan sponsors in the United States with respect to the contraceptive Mandate. But, as discussed below, governmental employers are permitted to respect an individual's objection under § 147.132(b) and thus to provide health insurance coverage without the objected-to contraceptive coverage to such individual. Where that exemption is operative, the Guidelines may not be construed to prevent a willing governmental plan sponsor of a group health plan from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

By the general extension of the exemption to the plans of plan sponsors in § 147.132(a)(1)(i), these interim final rules also exempt group health plans sponsored by an entity other than an employer (for example, a union) that objects based on sincerely held religious beliefs to coverage of contraceptives or sterilization.

7. Section 147.132(a)(1)(ii)

As in the previous rules, the plans of institutions of higher education that arrange student health insurance coverage will continue to be treated similarly to the way in which the plans of employers are treated, but for the purposes of such plans being exempt or electing the optional accommodation, rather than merely being eligible for the accommodation as in the previous rule. These interim final rules specify, in § 147.132(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor. As mentioned above, because the Affordable Care Act does not require institutions of higher education to arrange student coverage, some institutions of higher education that object to the Mandate appear to have chosen to stop arranging student plans rather than comply with the Mandate or use the accommodation. Extending the exemption in these interim final rules may remove an obstacle to such entities deciding to offer student plans, thereby giving students another health insurance option.

E. Exemption for Issuers

These interim final rules extend the exemption, in § 147.132(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own religious objections to providing coverage for contraceptive services.

The Departments are not currently aware of health insurance issuers that possess their own religious objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations are protected from being required to provide coverage or pay for abortions. See, for example, Consolidated Appropriations Act of 2017, Public Law 115–31, Div. H, Title V, Sec. 507(d). Congress also declared this year that "it is the intent of Congress" to include a "conscience clause" which provides exceptions for religious beliefs if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans." See *Id.* at Div. C, Title VIII, Sec. 808. In light of the clearly expressed intent of Congress to protect religious liberty, particularly in certain health care contexts, along with the specific efforts to protect issuers, the Departments have concluded that an exemption for issuers is appropriate.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.132(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. As set forth in these interim final rules, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection. Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under 42 CFR 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include coverage for some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt. Issuers that hold religious objections should identify to plan sponsors the lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers' sincerely held religious beliefs, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Permitting issuers to object to offering contraceptive coverage based on sincerely held religious beliefs will allow issuers to

continue to offer coverage to plan sponsors and individuals, without subjecting them to liability under section 2713(a)(4) of the PHS Act or related provisions for their failure to provide contraceptive coverage.

The issuer exemption does not specifically include third party administrators, although the optional accommodation process provided under these interim final rules specifies that third party administrators cannot be required to contract with an entity that invokes that process. Some religious third party administrators have brought suit in conjunction with suits brought by organizations enrolled in ERISA-exempt church plans. Such plans are now exempt under these interim final rules, and their third party administrators, as claims processors, are under no obligation under section 2713(a)(4) of the PHS Act to provide benefits for contraceptive services, as that section applies only to plans and issuers. In the case of ERISA-covered plans, plan administrators are obligated under ERISA to follow the plan terms, but it is the Departments' understanding that third party administrators are not typically designated as plan administrators under section 3(16) of ERISA and, therefore, would not normally act as plan administrators under section 3(16) of ERISA. Therefore, to the Departments' knowledge, it is only under the existing accommodation process that third party administrators are required to undertake any obligations to provide or arrange for contraceptive coverage to which they might object. These interim final rules make the accommodation process optional for employers and other plan sponsors, and specify that third party administrators that have their own objection to complying with the accommodation process may decline to enter into, or continue, contracts as third party administrators of such plans. For these reasons, these interim final rules do not otherwise exempt third party administrators. The Departments solicit public comment, however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have religious beliefs implicated by the Mandate.

F. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.132(a)(2). That paragraph specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.132(a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

G. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the "individual exemption"). Section 147.132(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a) (1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held religious beliefs. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer religiously acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' religious beliefs, or against the individual employees who accept such offers. See *Wieland*, 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the objections of individual employees by offering them plans that omit contraceptive coverage, even if those governmental entities do not object to offering contraceptive coverage in general.

This "individual exemption" cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of State law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held religious objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other Federal or State law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held religious beliefs.[62] At the same time, this individual exemption "does not undermine the governmental interests furthered by the contraceptive coverage requirement,"[63] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered.

H. Optional Accommodation

Despite expanding the scope of the exemption, these rules also keep the accommodation process, but revise it so as to make it optional. In this way, objecting employers are no longer required to choose between direct compliance or compliance through the accommodation. These rules maintain the location of the accommodation process in the Code of Federal Regulations at 45 CFR 147.131, 26 CFR 54.9815–2713A, and 29 CFR 2590.715–2713A. These rules, by virtue of expanding the plan sponsor exemption beyond houses of worship and integrated auxiliaries that were

[62] See, for example, *Wieland*, 196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130, where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to "forgo health insurance altogether."

[63] 78 FR 39874.

previously exempt, and beyond religious nonprofit groups that were previously accommodated, and by defining eligible organizations for the accommodation with reference to those covered by the exemption, likewise expand the kinds of entities that may use the optional accommodation. This includes plan sponsors with sincerely held religious beliefs for the reasons described above. Consequently, under these interim final rules, objecting employers may make use of the exemption, or may choose to pursue the optional accommodation process. If an eligible organization pursues the optional accommodation process through the EBSA Form 700 or other specified notice to HHS, it voluntarily shifts an obligation to provide separate but seamless contraceptive coverage to its issuer or third party administrator.

The fees adjustment process for qualifying health issuers or third party administrators pursuant to 45 CFR 156.50 is not modified, and (as specified therein) requires for its applicability that an exception under OMB Circular No. A–25R be in effect as the Secretary of the Department of Health and Human Services requests.

If an eligible organization wishes to revoke its use of the accommodation, it can do so under these interim final rules and operate under its exempt status. As part of its revocation, the issuer or third party administrator of the eligible organization must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. This revocation process applies both prospectively to eligible organizations who decide at a later date to avail themselves of the optional accommodation and then decide to revoke that accommodation, as well as to organizations that were included in the accommodation prior to the effective date of these interim final rules either by their submission of an EBSA Form 700 or notification, or by some other means under which their third party administrator or issuer was notified by DOL or HHS that the accommodation applies. Consistent with other applicable laws, the issuer or third party administrator of an eligible organization must promptly notify plan participants and beneficiaries of the change of status to the extent such participants and beneficiaries are currently being offered contraceptive coverage at the time the accommodated organization invokes its exemption. If contraceptive coverage is being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the 1st day of the 1st plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act,[64] if applicable, to revoke its use of the accommodation process.

The Departments have eliminated the provision in the previous accommodation under which an issuer is deemed to have complied with the Mandate where the issuer relied reasonably and in good faith on a representation by an eligible organization as to its eligibility for the accommodation, even if that representation was later determined to be incorrect. Because any organization with a sincerely held religious objection to contraceptive coverage is now eligible for the optional accommodation under these interim final rules and is also exempt, the Departments believe there is minimal opportunity for mistake or misrepresentation by the organization, and the reliance provision is no longer necessary.

I. Definition of Contraceptive Services for the Purpose of These Rules

The interim final rules specify that when the rules refer to "contraceptive" services, benefits, or coverage, such terms include contraceptive or sterilization items, services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv). This was the case under the previous rules, as expressed in the preamble text of the various iterations of the regulations, but the Departments wish to make the scope clear by specifying it in the regulatory text.

J. Conclusion

The Departments believe that the Guidelines and the exemptions expanded herein will advance the limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress' well-established record of allowing for religious exemptions with respect to especially sensitive health care and health insurance requirements. These interim final rules leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. These interim final rules also maintain HRSA's discretion to decide whether to continue to require contraceptive coverage under the Guidelines (in plans where Congress applied section 2713 of the PHS Act) if no objection exists. The Departments believe this array of programs and requirements better serves the interest of providing contraceptive coverage while protecting the conscience rights of entities that have sincerely held religious objections to some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

V. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; 79 FR 51092).

Section 553(b) of the Administrative Procedure Act (APA) requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated

[64] See also 26 CFR 54.9815–2715(b); 29 CFR 2590.715–2715(b); 45 CFR 147.200(b).

those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to continue to update the Guidelines.

Dozens of lawsuits over the Mandate have been pending for nearly 5 years. The Supreme Court remanded several of those cases more than a year ago, stating that on remand "[w]e anticipate that the Courts of Appeals will allow the parties sufficient time to resolve any outstanding issues between them". *Zubik*, 136 S. Ct. at 1560. During that time, Courts of Appeals have been asking the parties in those cases to submit status reports every 30 through 90 days. Those status reports have informed the courts that the parties were in discussions, and about the RFI issued in late 2016 and its subsequent comment process and the FAQ the Departments issued indicating that we could not find a way at that time to amend the accommodation process so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. Since then, several courts have issued orders setting more pressing deadlines. For example, on March 10, 2017, the United States Court of Appeals for the Seventh Circuit ordered that, by May 1, 2017, "the court expects to see either a report of an agreement to resolve the case or detailed reports on the parties' respective positions. In the event no agreement is reported on or before May 1, 2017, the court will plan to schedule oral argument on the merits of the case on short notice after that date". The Departments submitted a status report but were unable to set forth their specific position because this interim final rule was not yet on public display. Instead, the Departments informed the Court that we "are now considering whether further administrative action would be appropriate". In response, the court extended the deadline to June 1, 2017, again declaring the court expected "to see either a report of an agreement to resolve the case or detailed reports on the parties' respective positions". The Departments were again unable to set forth their position in that status report, but were able to state that the "Departments of Health and Human Services, Labor, and the Treasury are engaged in rulemaking to reconsider the regulations at issue here," citing *https://www.reginfo.gov/public/do/eoDetails?rrid=127381*.

As discussed above, the Departments have concluded that, in many instances, requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncomplaince has violated RFRA. Good cause exists to issue the expanded exemption in these interim final rules in order to cure such violations (whether among litigants or among similarly situated parties that have not litigated), to help settle or resolve cases, and to ensure, moving forward, that our regulations are consistent with any approach we have taken in resolving certain litigation matters.

The Departments have also been subject to temporary injunctions protecting many religious nonprofit organizations from being subject to the accommodation process against their wishes, while many other organizations are fully exempt, have permanent court orders blocking the contraceptive coverage requirement, or are not subject to section 2713 of the PHS Act and its enforcement due to Congress' limited application of that requirement. Good cause exists to change the Departments' previous rules to direct HRSA to bring its Guidelines in accord with the legal realities and remove the threat of a future violation of religious beliefs, including where such violations are contrary to Federal law.

Other objecting entities similarly have not had the protection of court injunctions. This includes some nonprofit entities that have sued the Departments, but it also includes some organizations that do not have lawsuits pending against us. For example, many of the closely held for-profit companies that brought the array of lawsuits challenging the Mandate leading up to the decision in *Hobby Lobby* are not protected by injunctions from the current rules, including the requirement that they either fully comply with the Mandate or subject themselves to the accommodation. Continuing to apply the Mandate's regulatory burden on individuals and organizations with religious beliefs against it could serve as a deterrent for citizens who might consider forming new entities—nonprofit or for-profit—and to offering health insurance in employer-sponsored plans or plans arranged by institutions of higher education. Delaying the protection afforded by these interim final rules would be contrary to the public interest because it would serve to extend for many months the harm caused to all entities and individuals with religious objections to the Mandate. Good cause exists to provide immediate resolution to this myriad of situations rather than leaving them to continued uncertainty, inconsistency, and cost during litigation challenging the previous rules.

These interim final rules provide a specific policy resolution that courts have been waiting to receive from the Departments for more than a year. If the Departments were to publish a notice of proposed rulemaking instead of these interim final rules, many more months could pass before the current Mandate is lifted from the entities receiving the expanded exemption, during which time those entities would be deprived of the relief clearly set forth in these interim final rules. In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and by what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed.

As the United States Court of Appeals for the D.C. Circuit stated with respect to an earlier interim final rule promulgated with respect to this issue in *Priests for Life* v. *U.S. Department of Health and Human Services*, 772 F.3d 229, 276 (D.C. Cir. 2014), vacated on other grounds, *Zubik* v. *Burwell*, 136 S. Ct. 1557 (2016), "[S]everal reasons support HHS's decision not to engage in notice and comment here". Among other things, the Court noted that "the agency made a good cause finding in the rule it issued"; that "the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues"; that "HHS will expose its interim rule to notice and comment before its permanent implementation"; and that "delay in implementation of the rule would interfere with the prompt availability of contraceptive coverage and delay the implementation of the alternative opt-out for religious objectors". *Id.* at 277.

Delaying the availability of the expanded exemption would delay the ability of those organizations and individuals to avail themselves of the relief afforded by these interim final rules. Good cause is supported by

providing relief for entities and individuals for whom the Mandate operates in violation of their sincerely held religious beliefs, but who would have to experience that burden for many more months under the prior regulations if these rules are not issued on an interim final basis. Good cause is also supported by the effect of these interim final rules in bringing to a close the uncertainty caused by years of litigation and regulatory changes made under section 2713(a)(4) of the PHS Act. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

Delaying the availability of the expanded exemption would also increase the costs of health insurance. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover contraception. They wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. They are refraining from making those changes—and therefore are continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. Issuing these rules on an interim final basis is necessary in order to help reduce the costs of health insurance for such entities and their plan participants.

These interim final rules also set forth an optional accommodation process, and expand eligibility for that process to a broader category of entities. Delaying the availability of the optional accommodation process would delay the ability of organizations that do not now qualify for the accommodation, but wish to opt into it, to be able to do so and therefore to provide a mechanism for contraceptive coverage to be provided to their employees while the organization's religious objections are accommodated.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final rules effective immediately upon filing at the Office of the Federal Register.

VI. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96 354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an "economically significant" regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of $100 million or more in any 1 year, and therefore do not meet the definition of "economically significant" under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations, and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations to expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, and to revise the accommodation process to make it optional for eligible organizations. The expanded exemption would apply to individuals and entities that have religious objections to some (or all) of the contraceptive and/or sterilization services that would be covered under the Guidelines. Such action is taken, among other reasons, to provide for participation in the health insurance market by certain entities or individuals free from penalties for violating sincerely held religious beliefs opposed to providing or receiving coverage of contraceptive services, and to resolve many of the lawsuits that have been filed against the Departments.

2. Anticipated Effects

The Departments assess this interim final rule together with a companion interim final rule concerning moral but non-religious conscientious objections to contraception, published elsewhere in this **Federal Register**. Regarding entities that are extended an exemption, absent expansion of the exemption the Guidelines would require many of these entities and individuals to either: Pay for coverage of contraceptive services that they find religiously objectionable; submit self-certifications that would result in their issuer or third party administrator paying for such services for their employees, which some entities also believe entangles them in the provision of such objectionable coverage; or, pay tax penalties or be

subject to other adverse consequences for non-compliance with these requirements. These interim final rules remove certain associated burdens imposed on these entities and individuals—that is, by recognizing their religious objections and exempting them—on the basis of such objections—from the contraceptive and/or sterilization coverage requirement of the HRSA Guidelines and making the accommodation process optional for eligible organizations.

To the extent that entities choose to revoke their accommodated status to make use of the expanded exemption immediately, a notice will need to be sent to enrollees (either by the entity or by the issuer or third party administrator) that their contraceptive coverage is changing, and guidance will reflect that such a notice requirement is imposed no more than is already required by preexisting rules that require notices to be sent to enrollees of changes to coverage during a plan year. If the entities wait until the start of their next plan year to change to exempt status, instead of doing so during a plan year, those entities generally will also be able to avoid sending any supplementary notices in addition to what they would otherwise normally send prior to the start of a new plan year. Additionally, these interim final rules provide such entities with an offsetting regulatory benefit by the exemption itself and its relief of burdens on their religious beliefs. As discussed below, assuming that more than half of entities that have been using the previous accommodation will seek immediate revocation of their accommodated status and notices will be sent to all their enrollees, the total estimated cost of sending those notices will be $51,990.

The Departments estimate that these interim final rules will not result in any additional burdens or costs on issuers or third party administrators. As discussed below, the Departments believe that 109 of the 209 entities making use of the accommodation process will instead make use of their newly exempt status. In contrast, the Departments expect that a much smaller number (which we assume to be 9) will make use of the accommodation that were not provided access to it previously. Reduced burdens for issuers and third party administrators due to reductions in use of the accommodation will more than offset increased obligations on issuers and third party administrators serving the fewer number of entities that will newly opt into the accommodation. This will lead to a net decrease in burdens and costs on issuers and third party administrators, who will no longer have continuing obligations imposed on them by the accommodation.

These interim final rules will result in some persons covered in plans of newly exempt entities not receiving coverage or payments for contraceptive services. The Departments do not have sufficient data to determine the actual effect of these rules on plan participants and beneficiaries, including for costs they may incur for contraceptive coverage, nor of unintended pregnancies that may occur. As discussed above and for reasons explained here, there are multiple levels of uncertainty involved in measuring the effect of the expanded exemption, including but not limited to—

- How many entities will make use of their newly exempt status.
- how many entities will opt into the accommodation maintained by these rules, under which their plan participants will continue receiving contraceptive coverage.
- which contraceptive methods some newly exempt entities will continue to provide without cost-sharing despite the entity objecting to other methods (for example, as reflected in *Hobby Lobby*, several objecting entities still provide coverage for 14 of the 18 women's contraceptive or sterilization methods, 134 S. Ct. at 2766).
- how many women will be covered by plans of entities using their newly exempt status.
- which of the women covered by those plans want and would have used contraceptive coverage or payments for contraceptive methods that are no longer covered by such plans.
- whether, given the broad availability of contraceptives and their relatively low cost, such women will obtain and use contraception even if it is not covered.
- the degree to which such women are in the category of women identified by IOM as most at risk of unintended pregnancy.
- the degree to which unintended pregnancies may result among those women, which would be attributable as an effect of these rules only if the women did not otherwise use contraception or a particular contraceptive method due to their plan making use of its newly exempt status.
- the degree to which such unintended pregnancies may be associated with negative health effects, or whether such effects may be offset by other factors, such as the fact that those women will be otherwise enrolled in insurance coverage.
- the extent to which such women will qualify for alternative sources of contraceptive access, such as through a parent's or spouse's plan, or through one of the many governmental programs that subsidize contraceptive coverage to supplement their access.

The Departments have access to sources of information discussed in the following paragraphs that are relevant to this issue, but those sources do not provide a full picture of the impact of these interim final rules.

First, the prior rules already exempted certain houses of worship and their integrated auxiliaries. Further, as discussed above, the prior accommodation process allows hundreds of additional religious nonprofit organizations in self-insured church plans that are exempt from ERISA to file a self-certification or notice that relieves not only themselves but, in effect, their third party administrators of any obligation to provide contraceptive coverage or payments. Although in the latter case, third party administrators are legally permitted to provide the coverage, several self-insured church plans themselves have expressed an objection in litigation to allowing such contraceptive coverage to be provided, and according to information received during litigation, it appears that such contraceptive coverage has not been provided. In addition, a significant portion of the lawsuits challenging the Mandate were brought by a single firm representing Catholic dioceses and related entities covered by their diocese-sponsored plans. In that litigation, the Departments took the position that, where those diocese-sponsored plans are self-insured, those plans are likely church plans exempt from ERISA.[65] For the purposes of considering whether the expanded exemption in these rules affects the persons covered by such diocese-sponsored plans, the Departments continue to assume that such plans are similar to other objecting entities using self-insured church plans with respect to their third party administrators being unlikely to provide contraceptive coverage to plan participants and beneficiaries under the previous rule. Therefore the

[65] See, for example, Brief in Opp. To Pls.' Mot. for Prelim. Inj., *Brandt* v. *Burwell*, No. 2:14–cv–681–AJS, doc. #23 (W.D. Pa. filed June 10, 2014) (arguing that "plaintiffs have not established an injury in fact to the degree plaintiffs have a self-insured church plan," based on the fact that "the same law firm representing the plaintiffs here has suggested in another similar case that all 'Catholic entities like the Archdiocese participate in "church plans."'"); *Roman Catholic Archdiocese of N.Y.* v. *Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013) ("because plaintiffs' self-insured plans are church plans, their third party administrators would not be required to provide contraceptive coverage").

Departments estimate that these interim final rules have no significant effect on the contraceptive coverage of women covered by plans of houses of worship and their integrated auxiliaries, entities using a self-insured church plan, or church dioceses sponsoring self-insured plans.

It is possible that an even greater number of litigating or accommodated plans might have made use of self-insured church plan status under the previous accommodation. Notably, one of the largest nonprofit employers that had filed suit challenging the Mandate had, under these prior rules, shifted most of their employees into self-insured church plans, and the Departments have taken the position that various other employers that filed suit were eligible to assume self-insured church plan status.[66] The Supreme Court's recent decision in *Advocate Health Care Network,* while not involving this Mandate, also clarifies certain circumstances under which religious hospitals may be eligible for self-insured church plan status. See 137 S. Ct. at 1656–57, 1663 (holding that a church plan under ERISA can be a plan not established and maintained by a church, if it is maintained by a principal-purpose organization).

Second, when the Departments previously created the exemption, expanded its application, and provided an accommodation (which, as mentioned, can lift obligations on self-insured church plans for hundreds of nonprofit organizations), we concluded that no significant burden or costs would result at all. (76 FR 46625; 78 FR 39889.) We reached this conclusion despite the impact, just described, whereby the previous rule apparently lead to women not receiving contraceptive coverage through hundreds of nonprofit entities using self-insured church plans. We also reached this conclusion without counting any significant burden or cost to some women covered in the plans of houses of worship or integrated auxiliaries that might want contraceptive coverage. This conclusion was based in part on the assertion, set forth in previous regulations, that employees of houses of worship and integrated auxiliaries likely share their employers' opposition to contraception. Many other religious nonprofit entities, however, both adopt and implement religious principles with similar fervency. For the reasons discussed above, the Departments no longer believe we can distinguish many of the women covered in the plans of religious nonprofit entities from the women covered in the plans of houses of worship and integrated auxiliaries regarding which the Departments assumed share their employers' objection to contraception, nor from women covered in the plans of religious entities using self-insured church plans regarding which we chose not to calculate any anticipated effect even though we conceded we were not requiring their third party administrators to provide contraceptive coverage. In the estimates and assumptions below, we include the potential effect of these interim rules on women covered by such entities, in order to capture all of the anticipated effects of these rules.

Third, these interim final rules extend the exemption to for-profit entities. Among the for-profit employers that filed suit challenging the Mandate, the one with the most employees was *Hobby Lobby*.[67] As noted above, and like some similar entities, the plaintiffs in *Hobby Lobby* were willing to provide coverage with no cost sharing of various contraceptive services: 14 of 18 FDA-approved women's contraceptive and sterilization methods.[68] (134 S. Ct. at 2766.) The effect of expanding the exemption to for-profit entities is therefore mitigated to the extent many of the persons covered by such entities' plans may receive coverage for at least some contraceptive services. No publicly traded for-profit entities have filed lawsuits challenging the Mandate. The Departments agree with the Supreme Court's expectation in this regard: "it seems unlikely that the sort of corporate giants to which HHS refers will often assert RFRA claims. HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable". *Hobby Lobby,* 134 S. Ct. at 2774. Therefore, although publicly traded entities could make use of exempt status under these interim final rules, the Departments do not expect that very many will do so, as compared to the 87 religious closely held for-profit entities that brought litigation challenging the Mandate (some of which might be content with the accommodation).

Fourth, the Departments have a limited amount of information about entities that have made use of the accommodation process as set forth in the previous rules. HHS previously estimated that 209 entities would make use of the accommodation process. That estimate was based on HHS's observation in its August 2014 interim final rules and July 2015 final regulations that there were 122 eligible entities that had filed litigation challenging the accommodation process, and 87 closely held for-profit entities that had filed suit challenging the Mandate in general. (79 FR 51096; 80 FR 41336). The Departments acknowledged that entities that had not litigated might make use of the accommodation, but we stated we did not have better data to estimate how many might use the accommodation overall.

After issuing those rules, the Departments have not received complete data on the number of entities actually using the accommodation, because the accommodation does not require many accommodated entities to submit information to us. Our limited records indicate that approximately 63 entities have affirmatively submitted notices to HHS to use the accommodation. This includes some fully insured and some self-insured plans, but it does not include entities that may have used the accommodation by submitting an EBSA form 700 self-certification directly to their issuer or third party administrator. We have deemed some other entities as being subject to the accommodation through their litigation filings, but that might not have led to contraceptive coverage being

[66] See *https://www.franciscanhealth.org/sites/default/files/2015%20employee%20benefit%20booklet.pdf.*; see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius,* 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013).

[67] Verified Complaint ¶ 34, *Hobby Lobby Stores, Inc., et al.* v. *Sebelius,* No. 5:12–cv–01000–HE (Sept. 12, 2012 W.D. Okla.) (13,240 employees).

[68] By reference to the FDA Birth Control Guide's list of 18 birth control methods for women and 2 for men, *https://www.fda.gov/downloads/forconsumers/byaudience/forwomen/freepublications/ucm517406.pdf,* Hobby Lobby and entities with similar beliefs were not willing to cover: IUD copper; IUD with progestin; emergency contraceptive (Levonorgestrel); and emergency contraceptive (Ulipristal Acetate). See 134 S. Ct. at 2765–66. Hobby Lobby was willing to cover: Sterilization surgery for women; sterilization implant for women; implantable rod; shot/injection; oral contraceptives ("the Pill"—combined pill); oral contraceptives ("the Pill"—extended/continuous use/combined pill); oral contraceptives ("the Mini Pill"—progestin only); patch; vaginal contraceptive ring; diaphragm with spermicide; sponge with spermicide; cervical cap with spermicide; female condom; spermicide alone. *Id.* Among women using these 18 female contraceptive methods, 85 percent use the 14 methods that Hobby Lobby and entities with similar beliefs were willing to cover (22,446,000 out of 26,436,000), and "[t]he pill and female sterilization have been the two most commonly used methods since 1982." See Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

provided to persons covered in some of those plans, either because they are exempt as houses of worship or integrated auxiliaries, they are in self-insured church plans, or we were not aware of their issuers or third party administrators so as to send them letters obligating them to provide such coverage. Our records also indicate that 60 plans used the contraceptive user fees adjustments in the 2015 plan year, the last year for which we have data. This includes only self-insured plans, and it includes some plans that self-certified through submitting notices and other plans that, presumably, self-certified through the EBSA form 700.

These sets of data are not inconsistent with our previous estimate that 209 entities would use the accommodation, but they indicate that some non-litigating entities used the accommodation, and some litigating entities did not, possibly amounting to a similar number. For this reason, and because we do not have more complete data available, we believe the previous estimate of 209 accommodated entities is still the best estimate available for how many entities have used the accommodation under the previous rule. This assumes that the number of litigating entities that did not use the accommodation is approximately the same as the number of non-litigating entities that did use it.

In considering how many entities will use the voluntary accommodation moving forward—and how many will use the expanded exemption—we also do not have specific data. We expect the 122 nonprofit entities that specifically challenged the accommodation in court to use the expanded exemption. But, as noted above, we believe a significant number of them are not presently participating in the accommodation, and that some nonprofit entities in self-insured church plans are not providing contraceptive coverage through their third party administrators even if they are using the accommodation. Among the 87 for-profit entities that filed suit challenging the Mandate in general, few if any filed suit challenging the accommodation. We do not know how many of those entities are using the accommodation, how many may be complying with the Mandate fully, how many may be relying on court injunctions to do neither, or how many will use the expanded exemption moving forward. Among entities that never litigated but used the accommodation, we expect many but not all of them to continue using the accommodation, and we do not have data to estimate how many such entities there are or how many will choose either option.

Overall, therefore, without sufficient data to estimate what the estimated 209 previously accommodated entities will do under these interim final rules, we assume that just over half of them will use the expanded exemption, and just under half will continue their accommodated status under the voluntary process set forth in these rules. Specifically, we assume that 109 previously accommodated entities will make use of their exempt status, and 100 will continue using the accommodation. This estimate is based in part on our view that most litigating nonprofit entities would prefer the exemption to the accommodation, but that many of either have not been using the accommodation or, if they have been using it, it is not providing contraceptive coverage for women in their plans where they participate in self-insured church plans. This estimate is also consistent with our lack of knowledge of how many for-profit entities were using the accommodation and will choose the exemption or the accommodation, given that many of them did not bring legal challenges against the accommodation after *Hobby Lobby*. This estimate is further consistent with our view, explained in more detail below, that some entities that are using the accommodation and did not bring litigation will use the exemption, but many accommodated, non-litigating entities—including the ones with the largest relative workforces among accommodated entities—will continue using the accommodation. The Departments recognize that we do not have better data to estimate the effects of these interim final rules on such entities.

In addition to these factors, we recognize that the expanded exemption and accommodation are newly available to religious for-profit entities that are not closely held and some other plan sponsors. As explained above, the Departments believe religious for-profit entities that are not closely held may exist, or may wish to come into being. HHS does not anticipate that there will be significant number of such entities, and among those, we believe that very few if any will use the accommodation. All of the for-profit entities that have challenged the Mandate have been religious closely held entities.

It is also possible that religious nonprofit or closely held for-profit entities that were already eligible for the accommodation but did not previously use it will opt into it moving forward, but because they could have done so under the previous rules, their opting into the accommodation is not caused by these rules.

Without any data to estimate how many of any entities newly eligible for and interested in using the accommodation might exist, HHS assumes for the purposes of estimating the anticipated effect of these rules that less than 10 entities (9) will do so. Therefore, we estimate that 109 entities will use the voluntary accommodation moving forward, 100 of which were already using the previous accommodation, and that 109 entities that have been using the previous accommodation will use the expanded exemption instead.

Fifth, in attempting to estimate the anticipated effect of these interim final rules on women receiving contraceptive coverage, the Departments have limited information about the entities that have filed suit challenging the Mandate. Approximately 209 entities have brought suit challenging the Mandate over more than 5 years. They have included a broad range of nonprofit entities and closely held for-profit entities. We discuss a number of potentially relevant points:

First, the Departments do not believe that out-of-pocket litigation costs have been a significant barrier to entities choosing to file suit. Based on the Departments' knowledge of these cases through public sources and litigation, nearly all the entities were represented pro bono and were subject to little or no discovery during the cases, and multiple public interest law firms publicly provided legal services for entities willing to challenge the Mandate.[69] (It is noteworthy, however, that such pro bono arrangements and minimization of discovery do not eliminate 100 percent of the time costs of participating in litigation or, as discussed in more detail below, the potential for negative

[69] See, for example, Catholic Diocese of Pittsburgh, "Award-winning attorney 'humbled' by recognition." *Pittsburgh Catholic* ("Jones Day is doing the cases 'pro bono,' or voluntarily and without payment.") (quoting Paul M. Pohl, Partner, Jones Day), available at *http://diopitt.org/pittsburgh-catholic/award-winning-attorney-humbled-recognition*; "Little Sisters Fight for Religious Freedom," *National Review* (Oct. 2, 2013) ("the Becket Fund for Religious Liberty is representing us pro bono, as they do all their clients.") (quoting Sister Constance Veit, L.S.P., communications director for the Little Sisters of the Poor), available at *http://www.nationalreview.com/article/360103/little-sisters-fight-religious-freedom-interview*; Suzanne Cassidy, "Meet the major legal players in the Conestoga Wood Specialties Supreme Court case," *LancasterOnline* (Mar. 25, 2014) ("Cortman and the other lawyers arguing on behalf of Conestoga Wood Specialties and Hobby Lobby are offering their services pro bono."), available at *http://lancasteronline.com/news/local/meet-the-major-legal-players-in-the-conestoga-wood-specialties/article_302bc8e2-b379-11e3-b669-001a4bcf6878.html*.

publicity. Both concerns could have dissuaded participation in lawsuits, and the potential for negative publicity may also dissuade participation in the expanded exemptions.)

Second, prior to the Affordable Care Act, the vast majority of entities already covered contraception, albeit not always without cost-sharing The Departments do not have data to indicate why entities that did not cover contraception prior to the Affordable Care Act chose not to cover it. As noted above, however, the Departments have maintained that compliance with the contraceptive Mandate is cost-neutral to issuers, which indicates that no significant financial incentive exists to omit contraceptive coverage. As indicated by the report by HHS ASPE discussed above, we have assumed that millions of women received preventive services after the Mandate went into effect because nearly all entities complied with the Guidelines. We are not aware of expressions from most of those entities indicating that they would have sincerely held religious objections to complying with the Mandate, and therefore that they would make use of the expanded exemption provided here.

Third, omitting contraceptive coverage has subjected some entities to serious public criticism and in some cases organized boycotts or opposition campaigns that have been reported in various media and online outlets regarding entities that have filed suit. The Departments expect that even if some entities might not receive such criticism, many entities will be reluctant to use the expanded exemption unless they are committed to their views to a significant degree.

Overall, the Departments do not know how many entities will use the expanded exemption. We expect that some non-litigating entities will use it, but given the aforementioned considerations, we believe it might not be very many more. Moreover, many litigating entities are already exempt or are not providing contraceptive coverage to women in their plans due to their participating in self-insured church plans, so the effect of the expanded exemption among litigating entities is significantly lower than it would be if all the women in their plans were already receiving the coverage.

To calculate the anticipated effects of this rule on contraceptive coverage among women covered by plans provided by litigating entities, we start by examining court documents and other public sources.[70] These sources provide some information, albeit incomplete, about how many people are employed by these entities. As noted above, however, contraceptive coverage among the employees of many litigating entities will not be affected by these rules because some litigating entities were exempt under the prior rule, while others were or appeared to be in self-insured church plans so that women covered in their plans were already not receiving contraceptive coverage.

Among litigating entities that were neither exempt nor likely using self-insured church plans, our best estimate based on court documents and public sources is that such entities employed approximately 65,000 persons, male and female.[71] The average number of workers at firms offering health benefits that are actually covered by those benefits is 62 percent.[72] This amounts to approximately 34,000 employees covered under those plans. DOL estimates that for each employee policyholder, there is approximately one dependent.[73] This amounts to approximately 68,000 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—compose 20.2 percent of the general population.[74] In addition, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines.[75] Therefore, we estimate that approximately 7,221 women of childbearing age that use contraception covered by the Guidelines are covered by employer sponsored plans of entities that have filed lawsuits challenging the Mandate, where those plans are neither exempt under the prior rule nor are self-insured church plans.

We also estimate that for the educational institutions objecting to the Mandate as applied to student coverage that they arranged, where the entities were neither exempt under the prior rule nor were their student plans self-insured, such student plans likely covered approximately 3,300 students. On average, we expect that approximately half of those students (1,650) are female. For the purposes of this estimate, we also assume that female policyholders covered by plans arranged by institutions of higher education are women of childbearing age. We expect that they would have less than the average number of dependents per policyholder than exists in standard plans, but for the purposes of providing an upper bound to this estimate, we assume that they would have an average of one dependent per policyholder, thus bringing the number of policyholders and dependents back up to 3,300. Many of those dependents are likely not to be women of childbearing age, but in order to provide an upper bound to this estimate, we assume they are. Therefore, for the purposes of this estimate, we assume that the effect of these expanded exemptions on student plans of litigating entities includes 3,300 women. Assuming that 44.3 perecent of such women use contraception covered by the Guidelines,[76] we estimate that

[70] Where complaints, affidavits, or other documents filed in court did not indicate the number of employees that work for an entity, and that entity was not apparently exempt as a house of worship or integrated auxiliary, and it was not using the kind of plan that we have stated in litigation qualifies for self-insured church plan status (see, for example, *Roman Catholic Archdiocese of N.Y.* v. *Sebelius*, 987 F. Supp. 2d 232, 242 (E.D.N.Y. 2013)), we examined employment data contained in some IRS form W–3's that are publicly available online for certain nonprofit groups, and looked at other Web sites discussing the number of people employed at certain entities.

[71] In a small number of lawsuits, named plaintiffs include organizations claiming to have members that seek an exemption. We have very little information about the number, size, and types of entities those members. Based on limited information from those cases, however, their membership appears to consist mainly, although not entirely, of houses of worship, integrated auxiliaries, and participants in self-insured plans of churches. As explained above, the contraceptive coverage of women covered by such plans is not likely to be affected by the expanded exemption in these rules. However, to account for plans subject to contraceptive coverage obligations among those members we have added 10,000 to our estimate of the number of persons among litigants that may be impacted by these rules.

[72] See Kaiser Family Foundation and Health Research and Educational Trust, "Employer Health Benefits: 2017 Annual Survey" at 57, available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[73] "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[74] United States Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." *https://www.hrsa.gov/womensguidelines/*; also, see 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. See, for example, Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[75] See *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states* (reporting that of 60,877,000 women aged 15–44, 26,945,000 use women's contraceptive methods covered by the Guidelines).

[76] It would appear that a smaller percentage of college-aged women use contraception—and use more expensive methods such as long acting methods or sterilization—than among other women of childbearing age. See NCHS Data Brief, "Current Contraceptive Status Among Women Aged 15–44: United States, 2011–2013" (Dec. 2014), available at

Continued

1,462 of those women would be affected by these rules.

Together, this leads the Departments to estimate that approximately 8,700 women of childbearing age may have their contraception costs affected by plans of litigating entities using these expanded exemptions. As noted above, the Departments do not have data indicating how many of those women agree with their employers' or educational institutions' opposition to contraception (so that fewer of them than the national average might actually use contraception). Nor do we know how many would have alternative contraceptive access from a parent's or spouse's plan, or from Federal, State, or local governmental programs, nor how many of those women would fall in the category of being most at risk of unintended pregnancy, nor how many of those entities would provide some contraception in their plans while only objecting to certain contraceptives.

Sixth, in a brief filed in the *Zubik* litigation, the Departments stated that "in 2014, [HHS] provided user-fee reductions to compensate TPAs for making contraceptive coverage available to more than 600,000 employees and beneficiaries," and that "[t]hat figure includes both men and women covered under the relevant plans." [77] HHS has reviewed the information giving rise to that estimate, and has received updated information for 2015. In 2014, 612,000 persons were covered by plans claiming contraceptive user fees adjustments, and in 2015, 576,000 persons were covered by such plans. These numbers include all persons in such plans, not just women of childbearing age.

HHS's information indicates that religious nonprofit hospitals or health systems sponsored a significant minority of the accommodated self-insured plans that were using contraceptive user fees adjustments, yet those plans covered more than 80 percent of the persons covered in all plans using contraceptive user fees adjustments. Some of those plans cover nearly 100,000 persons each, and several others cover approximately 40,000 persons each. In other words, these plans were proportionately much larger than the plans provided by other entities using the contraceptive user fees adjustments.

There are two reasons to believe that a significant fraction of the persons covered by previously accommodated plans provided by religious nonprofit hospitals or health systems may not be affected by the expanded exemption. A broad range of religious hospitals or health systems have publicly indicated that they do not conscientiously oppose participating in the accommodation.[78] Of course, some of these religious hospitals or health systems may opt for the expanded exemption under these interim final rules, but others might not. In addition, among plans of religious nonprofit hospitals or health systems, some have indicated that they might be eligible for status as a self-insured church plan.[79] As discussed above, some litigants challenging the Mandate have appeared, after their complaints were filed, to make use of self-insured church plan status.[80] (The Departments take no view on the status of these particular plans under ERISA, but simply make this observation for the purpose of seeking to estimate the impact of these interim final rules.) Nevertheless, overall it seems likely that many of the remaining religious hospital or health systems plans previously using the accommodation will continue to opt into the voluntary accommodation under these interim final rules, under which their employees will still receive contraceptive coverage. To the extent that plans of religious hospitals or health systems are able to make use of self-insured church plan status, the previous accommodation rule would already have allowed them to relieve themselves and their third party administrators of obligations to provide contraceptive coverage or payments. Therefore, in such situations these interim final rules would not have an anticipated effect on the contraceptive coverage of women in those plans.

Considering all these data points and limitations, the Departments offer the following estimate of the number of women who will be impacted by the expanded exemption in these interim final rules. The Departments begin with the 8,700 women of childbearing age that use contraception who we estimate will be affected by use of the expanded exemption among litigating entities. In addition to that number, we calculate the following number of women affected by accommodated entities using the expanded exemption. As noted above, approximately 576,000 plan participants and beneficiaries were covered by self-insured plans that received contraceptive user fee adjustments in 2014. Although additional self-insured entities may have participated in the accommodation without making use of contraceptive user fees adjustments, we do not know what number of entities did so. We consider it likely that self-insured entities with relatively larger numbers of covered persons had sufficient financial incentive to make use of the contraceptive user fees adjustments. Therefore, without better data available, we assume that the number of persons covered by self-insured plans using contraceptive user fees adjustments approximates the number of persons covered by all self-insured plans using the accommodation.

An additional but unknown number of persons were likely covered in fully insured plans using the accommodation. The Departments do not have data on how many fully insured plans have been using the accommodation, nor on how many persons were covered by those plans. DOL estimates that, among persons covered by employer sponsored insurance, 56.1 percent are covered by self-insured plans and 43.9 percent are covered by fully insured plans.[81] Therefore, corresponding to the 576,000 persons covered by self-insured plans using user fee adjustments, we estimate an additional 451,000 persons were covered by fully insured plans using the accommodation. This yields an estimate of 1,027,000 covered persons of all ages and sexes in plans using the previous accommodation.

As discussed below, and recognizing the limited data available for our estimates, the Departments estimate that 100 of the 209 entities that were using the accommodation under the prior rule

https://www.cdc.gov/nchs/data/databriefs/db173.pdf.

[77] Brief of Respondents at 18–19 & n.7, *Zubik* v. *Burwell*, No. 14–1418, et al. (U.S. filed Feb. 10, 2016). The actual number is 612,487.

[78] See, for example, *https://www.chausa.org/newsroom/women%27s-preventive-health-services-final-rule* ("HHS has now established an accommodation that will allow our ministries to continue offering health insurance plans for their employees as they have always done. . . . We are pleased that our members now have an accommodation that will not require them to contract, provide, pay or refer for contraceptive coverage. . . . We will work with our members to implement this accommodation.") In comments submitted in previous rules concerning this Mandate, the Catholic Health Association has stated it "is the national leadership organization for the Catholic health ministry, consisting of more than 2,000 Catholic health care sponsors, systems, hospitals, long-term care facilities, and related organizations. Our ministry is represented in all 50 states and the District of Columbia." Comments on CMS–9968–ANPRM (dated June 15, 2012).

[79] See, for example, Brief of the Catholic Health Association of the United States as Amicus Curiae in Support of Petitioners, *Advocate Health Care Network*, Nos. 16–74, 16–86, 16–258, 2017 WL 371934 at *1 (U.S. filed Jan. 24, 2017) ("CHA members have relied for decades that the 'church plan' exemption contained in" ERISA.).

[80] See supra note 66.

[81] "Health Insurance Coverage Bulletin" Table 3A, page 15. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

will continue to opt into it under these interim final rules. Notably, however, the data concerning accommodated self-insured plans indicates that plans sponsored by religious hospitals and health systems encompass more than 80 percent of the persons covered in such plans. In other words, plans sponsored by such entities have a proportionately larger number of covered persons than do plans sponsored by other accommodated entities, which have smaller numbers of covered persons. As also cited above, many religious hospitals and health systems have indicated that they do not object to the accommodation, and some of those entities might also qualify as self-insured church plans, so that these interim final rules would not impact the contraceptive coverage their employees receive. We do not have specific data on which plans of which sizes will actually continue to opt into the accommodation, nor how many will make use of self-insured church plan status. We assume that the proportions of covered persons in self-insured plans using contraceptive user fees adjustments also apply in fully insured plans, for which we lack representative data. Based on these assumptions and without better data available, we assume that the 100 accommodated entities that will remain in the accommodation will account for 75 percent of all the persons previously covered in accommodated plans. In comparison, we assume the 109 accommodated entities that will make use of the expanded exemption will encompass 25 percent of persons previously covered in accommodated plans.

Applying these percentages to the total number of 1,027,000 persons we estimate are covered in accommodated plans, we estimate that approximately 257,000 persons previously covered in accommodated plans will be covered in the 109 plans that use the expanded exemption, and 770,000 persons will be covered in the estimated 100 plans that continue to use the accommodation. According to the Census data cited above, 20.2 percent of these persons are women of childbearing age, which amounts to approximately 51,900 women of childbearing age in previously accommodated plans that we estimate will use the expanded exemption. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, so that we expect approximately 23,000 women that use contraception covered by the Guidelines to be affected by accommodated entities using the expanded exemption.

It is not clear the extent to which this number overlaps with the number estimated above of 8,700 women in plans of litigating entities that may be affected by these rules. Based on our limited information from the litigation and accommodation notices, we expect that the overlap is significant. Nevertheless, in order to estimate the possible effects of these rules, we assume there is no overlap between these two numbers, and therefore that these interim final rules would affect the contraceptive costs of approximately 31,700 women.

Under the assumptions just discussed, the number of women whose contraceptive costs will be impacted by the expanded exemption in these interim final rules is less than 0.1 percent of the 55.6 million women in private plans that HHS ASPE estimated [82] receive preventive services coverage under the Guidelines.

In order to estimate the cost of contraception to women affected by the expanded exemption, the Departments are aware that, under the prior accommodation process, the total user fee adjustment amount for self-insured plans for the 2015 benefit year was $33 million. These adjustments covered the cost of contraceptive coverage provided to women participants and beneficiaries in self-insured plans where the employer objected and made use of the accommodation, and where an authorizing exception under OMB Circular No. A–25R was in effect as the Secretary of the Department of Health and Human Services requests. Nine percent of that amount was attributable to administrative costs and margin, according to the provisions of 45 CFR 156.50(d)(3)(ii). Thus the amount of the adjustments attributable to the cost of contraceptive services was about $30 million. As discussed above, in 2015 that amount corresponded to 576,000 persons covered by such plans. Among those persons, as cited above, approximately 20.2 percent on average were women of childbearing age—that is, approximately 116,000 women. As noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines, which includes 51,400 women in those plans. Therefore, entities using contraceptive user fees adjustments received approximately $584 per year per woman of childbearing age that use contraception covered by the Guidelines and are covered in their plans.

As discussed above, the Departments estimate that the expanded exemptions will impact the contraceptive costs of approximately 31,700 women of childbearing age that use contraception covered by the Guidelines. At an average of $584 per year, the financial transfer effects attributable to the interim final rules on those women would be approximately $18.5 million.[83] [84]

To account for uncertainty in the estimate, we conducted a second analysis using an alternative framework, in order to thoroughly consider the possible upper bound economic impact of these interim final rules.

As noted above, the HHS ASPE report estimated that 55.6 million women aged 15 to 64 and covered by private insurance had preventive services coverage under the Affordable Care Act. Approximately 16.2 percent of those women were enrolled in plans on exchanges or were otherwise not covered by employer sponsored insurance, so only 46.6 million women aged 15 to 64 received the coverage through employer sponsored private insurance plans.[85] In addition, some of those private insurance plans were offered by government employers, encompassing approximately 10.5 million of those women aged 15 to 64.[86]

[82] Available at *https://aspe.hhs.gov/pdf-report/affordable-care-act-improving-access-preventive-services-millions-americans*; also, see Abridged Report, available at *https://www.womenspreventivehealth.org/wp-content/uploads/2017/01/WPSI_2016AbridgedReport.pdf.*

[83] As noted above, the Departments have taken the position that providing contraceptive coverage is cost neutral to issuers. (78 FR 39877). At the same time, because of the up-front costs of some contraceptive or sterilization methods, and because some entities did not cover contraception prior to the Affordable Care Act, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent × 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent.

[84] Describing this impact as a transfer reflects an implicit assumption that the same products and services would be used with or without the rule. Such an assumption is somewhat oversimplified because the interim final rules shift cost burden to consumption decision-makers (that is, the women who choose whether or not to use the relevant contraceptives) and thus can be expected to lead to some decrease in use of the affected drugs and devices and a potential increase in pregnancy—thus leading to a decrease and an increase, respectively, in medical expenditures.

[85] Available at *https://aspe.hhs.gov/system/files/pdf/139221/The%20Affordable%20Care%20Act%20is%20Improving%20Access%20to%20Preventive%20Services%20for%20Millions%20of%20Americans.pdf.*

[86] The ASPE study relied on Census data of private health insurance plans, which included plans sponsored by either private or public sector

Continued

The expanded exemption in these interim final rules does not apply to government plan sponsors. Thus we estimate that the number of women aged 15 to 64 covered by private sector employer sponsored insurance who receive preventive services coverage under the Affordable Care Act is approximately 36 million.

Prior to the implementation of the Affordable Care Act, approximately 6 percent of employer survey respondents did not offer contraceptive coverage, with 31 percent of respondents not knowing whether they offered such coverage.[87] The 6 percent may have included approximately 2.16 million of the women aged 15–64 covered by employer sponsored insurance plans in the private sector. According to Census data, 59.9 percent of women aged 15 to 64 are of childbearing age (aged 15 to 44), in this case, 1.3 million. And as noted above, approximately 44.3 percent of women of childbearing age use women's contraceptive methods covered by the Guidelines. Therefore we estimate that 574,000 women of childbearing age that use contraceptives covered by the Guidelines were covered by plans that omitted contraceptive coverage prior to the Affordable Care Act.[88]

It is unknown what motivated those employers to omit contraceptive coverage—whether they did so for conscientious reasons, or for other reasons. Despite our lack of information about their motives, we attempt to make a reasonable estimate of the upper bound of the number of those employers that omitted contraception before the Affordable Care Act and that would make use of these expanded exemptions based on sincerely held religious beliefs.

To begin, we estimate that publicly traded companies would not likely make use of these expanded exemptions. Even though the rule does not preclude publicly traded companies from dropping coverage based on a sincerely held religious belief, it is likely that attempts to object on religious grounds by publicly traded companies would be rare. The Departments take note of the Supreme Court's decision in *Hobby Lobby,* where the Court observed that "HHS has not pointed to any example of a publicly traded corporation asserting RFRA rights, and numerous practical restraints would likely prevent that from occurring. For example, the idea that unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs seems improbable". 134 S. Ct. at 2774. The Departments are aware of several Federal health care conscience laws[89] that in some cases have existed for decades and that protect companies, including publicly traded companies, from discrimination if, for example, they decline to facilitate abortion, but we are not aware of examples where publicly traded companies have made use of these exemptions. Thus, while we consider it important to include publicly traded companies in the scope of these expanded exemptions for reasons similar to those used by the Congress in RFRA and some health care conscience laws, in estimating the anticipated effects of the expanded exemptions we agree with the Supreme Court that it is improbable any will do so.

This assumption is significant because 31.3 percent of employees in the private sector work for publicly traded companies.[90] That means that only approximately 394,000 women aged 15 to 44 that use contraceptives covered by the Guidelines were covered by plans of non-publicly traded companies that did not provide contraceptive coverage pre-Affordable Care Act.

Moreover, these interim final rules build on existing rules that already exempt houses of worship and integrated auxiliaries and, as explained above, effectively remove obligations to provide contraceptive coverage within objecting self-insured church plans. These rules will therefore not effect transfers to women in the plans of such employers. In attempting to estimate the number of such employers, we consider the following information. Many Catholic dioceses have litigated or filed public comments opposing the Mandate, representing to the Departments and to courts around the country that official Catholic Church teaching opposes contraception. There are 17,651 Catholic parishes in the

employers. See Table 2, notes 2 & 3 (explaining the scope of private plans and government plans for purposes of Table 2), available at *https://www.census.gov/content/dam/Census/library/publications/2014/demo/p60-250.pdf.*

According to data tables from the Medical Expenditure Panel Survey (MEPS) of the Agency for Healthcare Research and Quality of HHS (*https://meps.ahrq.gov/mepsweb/*), State and local governments employ 19,297,960 persons; 99.2 percent of those employers offer health insurance; and 67.4 percent of employees that work at such entities where insurance is offered are enrolled in those plans, amounting to 12.9 million persons enrolled. DOL estimates that in the public sector, for each policyholder there is an average of slightly less than one dependent. "Health Insurance Coverage Bulletin" Table 4, page 21. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.* Therefore, State and local government employer plans cover approximately 24.8 million persons of all ages. Census data indicates that on average, 12 percent of persons covered by private insurance plans are aged 65 and older. Using these numbers, we estimate that State and local government employer plans cover approximately 21.9 million persons under age 65.

The Federal Government has approximately 8.2 million persons covered in its employee health plans. According to information we received from the Office of Personnel Management, this includes 2.1 million employees having 3.2 million dependents, and 1.9 million retirees (annuitants) having 1 million dependents. We do not have information about the ages of these policyholders and dependents, but for the purposes of this estimate we assume the annuitants and their dependents are aged 65 or older and the employees and their dependents are under age 65, so that the Federal Government's employee health plans cover 5.3 million persons under age 65.

Thus, overall we estimate there are 27.2 million persons under age 65 enrolled in private health insurance sponsored by government employers. Of those, 38.3 percent are women aged 15–64, that is, 10.5 million.

[87] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2010 Annual Survey" at 196, available at *https://kaiserfamilyfoundation.files.wordpress.com/2013/04/8085.pdf.*

[88] Some of the 31 percent of survey respondents that did not know about contraceptive coverage may not have offered such coverage. If it were possible to account for this non-coverage, the estimate of potentially affected covered women could increase. On the other hand, these employers' lack of knowledge about contraceptive coverage suggests that they lacked sincerely held religious beliefs specifically objecting to such coverage—beliefs without which they would not qualify for the expanded exemptions offered by these rules. In that case, omission of such employers and covered women from this estimation approach would be appropriate. Correspondingly, the 6 percent of employers that had direct knowledge about the absence of coverage may be more likely to have omitted such coverage on the basis of religious beliefs than were the 31 percent of survey respondents who did not know whether the coverage was offered. Yet an entity's mere knowledge about its coverage status does not itself reflect its motive for omitting coverage. In responding to the survey, the entity may have simply examined its plan document to determine whether or not contraceptive coverage was offered. As will be relevant in a later portion of the analysis, we have no data indicating what portion of the entities that omitted contraceptive coverage pre-Affordable Care Act did so on the basis of sincerely held religious beliefs, as opposed to doing so for other reasons that would not qualify them for the expanded exemption offered in these interim final rules.

[89] For example, 42 U.S.C. 300a–7(b), 42 U.S.C. 238n, and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31.

[90] John Asker, et al., "Corporate Investment and Stock Market Listing: A Puzzle?" 28 *Review of Financial Studies* Issue 2, at 342–390 (Oct. 7, 2014), available at *https://doi.org/10.1093/rfs/hhu077.* This is true even though there are only about 4,300 publicly traded companies in the U.S. See Rayhanul Ibrahim, "The number of publicly-traded US companies is down 46% in the past two decades," *Yahoo! Finance* (Aug. 8, 2016), available at *https://finance.yahoo.com/news/jp-startup-public-companies-fewer-000000709.html.*

United States,[91] 197 Catholic dioceses,[92] 5,224 Catholic elementary schools, and 1,205 Catholic secondary schools.[93] Not all Catholic schools are integrated auxiliaries of Catholic churches, but there are other Catholic entities that are integrated auxiliaries that are not schools, so we use the number of schools to estimate of the number of integrated auxiliaries. Among self-insured church plans that oppose the Mandate, the Department has been sued by two—Guidestone and Christian Brothers. Guidestone is a plan organized by the Southern Baptist convention. It covers 38,000 employers, some of which are exempt as churches or integrated auxiliaries, and some of which are not.[94] Christian Brothers is a plan that covers Catholic organizations. It covers Catholic churches and integrated auxiliaries, which are estimated above, but also it has said in litigation that it also covers about 500 additional entities that are not exempt as churches. In total, therefore, we estimate that approximately 62,000 employers among houses of worship, integrated auxiliaries, and church plans, were exempt or relieved of contraceptive coverage obligations under the previous rules. We do not know how many persons are covered in the plans of those employers. Guidestone reports that among its 38,000 employers, its plan covers approximately 220,000 persons, and its employers include "churches, mission-sending agencies, hospitals, educational institutions and other related ministries." Using that ratio, we estimate that the 62,000 church and church plan employers among Guidestone, Christian Brothers, and Catholic churches would include 359,000 persons. Among them, as referenced above, 72,500 would be of childbearing age, and 32,100 would use contraceptives covered by the Guidelines. Therefore, we estimate that the private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act, and that were not exempt by the previous rules nor were participants in self-insured church plans that oppose contraceptive coverage, covered 362,100 women aged 15 to 44 that use contraceptives covered by the Guidelines. As noted above, we estimate an average annual expenditure on contraceptive products and services of $584 per user. That would amount to $211.5 million in potential transfer impact among entities that did not cover contraception pre- Affordable Care Act for any reason.

We do not have data indicating how many of the entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held religious beliefs that might qualify them for exempt status under these interim final rules, as opposed to having done so for other reasons. Besides the entities that filed lawsuits or submitted public comments concerning previous rules on this matter, we are not aware of entities that omitted contraception pre-Affordable Care Act and then opposed the contraceptive coverage requirement after it was imposed by the Guidelines. For the following reasons, however, we believe that a reasonable estimate is that no more than approximately one third of the persons covered by relevant entities—that is, no more than approximately 120,000 affected women—would likely be subject to potential transfer impacts under the expanded religious exemptions offered in these interim final rules. Consequently, as explained below, we believe that the potential impact of these interim final rules falls substantially below the $100 million threshold for economically significant and major rules.

First, as mentioned, we are not aware of information that would lead us to estimate that all or most entities that omitted coverage of contraception pre-Affordable Care Act did so on the basis of sincerely held conscientious objections in general or religious beliefs specifically, as opposed to having done so for other reasons. Moreover, as suggested by the Guidestone data mentioned previously, employers with conscientious objections may tend to have relatively few employees. Also, avoiding negative publicity, the difficulty of taking away a fringe benefit that employees have become accustomed to having, and avoiding the administrative cost of renegotiating insurance contracts, all provide reasons for some employers not to return to pre-Affordable Care Act lack of contraceptive coverage. Additionally, as discussed above, many employers with objections to contraception, including several of the largest litigants, only object to some contraceptives and cover as many as 14 of 18 of the contraceptive methods included in the Guidelines. This will reduce, and potentially eliminate, the contraceptive cost transfer for women covered in their plans.[95] Furthermore, among nonprofit entities that object to the Mandate, it is possible that a greater share of their employees oppose contraception than among the general population, which should lead to a reduction in the estimate of how many women in those plans actually use contraception.

In addition, not all sincerely held conscientious objections to contraceptive coverage are likely to be held by persons with religious beliefs as distinct from persons with sincerely held non-religious moral convictions, whose objections would not be encompassed by these interim final rules.[96] We do not have data to indicate, among entities that did not cover contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, which ones did so based on religious beliefs and which ones did so instead based on non-religious moral convictions. Among the general public, polls vary about religious beliefs but one prominent poll shows that 89 percent of Americans say they believe in God, while 11 percent say they do not or are agnostic.[97] Therefore, we estimate that for every ten entities that omitted contraception pre-Affordable Care Act based on sincerely held conscientious objections as opposed to other reasons, one did so based on sincerely held non-religious moral convictions, and therefore are not affected by the expanded exemption provided by these interim final rules for religious beliefs.

Based on our estimate of an average annual expenditure on contraceptive products and services of $584 per user,

[91] Roman Catholic Diocese of Reno, "Diocese of Reno Directory: 2016–2017," available at *http://www.renodiocese.org/documents/2016/9/2016%202017%20directory.pdf.*

[92] Wikipedia, "List of Catholic dioceses in the United States," available at *https://en.wikipedia.org/wiki/List_of_Catholic_dioceses_in_the_United_States.*

[93] National Catholic Educational Association, "Catholic School Data," available at *http://www.ncea.org/NCEA/Proclaim/Catholic_School_Data/Catholic_School_Data.aspx.*

[94] Guidestone Financial Resources, "Who We Serve," available at *https://www.guidestone.org/AboutUs/WhoWeServe.*

[95] On the other hand, a key input in the approach that generated the one third threshold estimate was a survey indicating that six percent of employers did not provide contraceptive coverage pre-Affordable Care Act. Employers that covered some contraceptives pre-Affordable Care Act may have answered "yes" or "don't know" to the survey. In such cases, the potential transfer estimate has a tendency toward underestimation because the rule's effects on such women—causing their contraceptive coverage to be reduced from all 18 methods to some smaller subset—have been omitted from the calculation.

[96] Such objections may be encompassed by companion interim final rules published elsewhere in this **Federal Register**. Those rules, however, as an interim final matter, are more narrow in scope than these rules. For example, in providing expanded exemptions for plan sponsors, they do not encompass companies with certain publicly traded ownership interests.

[97] Gallup, "Most Americans Still Believe in God" (June 14–23, 2016), available at *http://www.gallup.com/poll/193271/americans-believe-god.aspx.*

the effect of the expanded exemptions on 120,000 women would give rise to approximately $70.1 million in potential transfer impact. This falls substantially below the $100 million threshold for economically significant and major rules. In addition, as noted above, premiums may be expected to adjust to reflect changes in coverage, thus partially offsetting the transfer experienced by women who use the affected contraceptives. As discussed elsewhere in this analysis, such women may make up approximately 8.9 percent (= 20.2 percent × 44.3 percent) of the covered population, in which case the offset would also be approximately 8.9 percent, yielding a potential transfer of $63.8 million.

We request comment on all aspects of the preceding regulatory impact analysis, as well as on how to attribute impacts to this interim final rule and the companion interim final rule concerning exemptions provided based on sincerely held (non-religious) moral convictions published elsewhere in this **Federal Register**.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments anticipate that there will be more entities reluctantly using the existing accommodation that will choose to operate under the newly expanded exemption, than entities that are not currently eligible to use the accommodation that will opt into it. The effect of this rule will therefore be that fewer overall adjustments are made to the Federally facilitated Exchange user fees for entities using the accommodation process, as long as the Secretary of the Department of Health and Human Services requests and an authorizing exception under OMB Circular No. A–25R is in effect, than would have occurred under the previous rule if this rule were not finalized. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities, and in many cases will relieve burdens and costs from such entities. By exempting from the Mandate small businesses and nonprofit organizations with religious objections to some (or all) contraceptives and/or sterilization, the Departments have reduced regulatory burden on such small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

However, we are requesting an emergency review of the information collection referenced later in this section. In compliance with the requirement of section 3506(c)(2)(A) of the PRA, we have submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting an emergency review and approval under both 5 CFR 1320.13(a)(2)(i) and (iii) of the implementing regulations of the PRA in order to implement provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). In accordance with 5 CFR 1320.13(a)(2)(i), we believe public harm is reasonably likely to ensue if the normal clearance procedures are followed. The use of normal clearance procedures is reasonably likely to prevent or disrupt the collection of information. Similarly, in accordance with 5 CFR 1320.13(a)(2)(iii), we believe the use of normal clearance procedures is reasonably likely to cause a statutory or court ordered deadline to be missed. Many cases have been on remand for over a year from the Supreme Court, asking the Departments and the parties to resolve this matter. These interim final rules extend exemptions to entities, which involves no collection of information and which the Departments have statutory authority to do by the use of interim final rules. If the information collection involved in the amended accommodation process is not approved on an emergency basis, newly exempt entities that wish to opt into the amended accommodation process might not be able to do so until normal clearance procedures are completed.

A description of the information collection provisions implicated in these interim final rules is given in the following section with an estimate of the annual burden. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.[98]

a. ICRs Regarding Self-Certification or Notices to HHS (§ 147.131(c)(3))

Each organization seeking to be treated as an eligible organization that wishes to use the optional accommodation process offered under

[98] May 2016 National Occupational Employment and Wage Estimates United States found at *https://www.bls.gov/oes/current/oes_nat.htm.*

these interim final rules must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these interim final rules continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, or to notify HHS, of their religious objection to coverage of all or a subset of contraceptive services, as set forth in the July 2015 final regulations. The burden related to the notice to HHS is currently approved under OMB Control Number 0938–1248 and the burden related to the self-certification (EBSA Form 700) is currently approved under OMB control number 0938–1292.

Notably, however, entities that are participating in the previous accommodation process, where a self-certification or notice has already been submitted, and where the entities choose to continue their accommodated status under these interim final rules, generally do not need to file a new self-certification or notice (unless they change their issuer or third party administrator). As explained above, HHS assumes that, among the 209 entities we estimated are using the previous accommodation, 109 will use the expanded exemption and 100 will continue under the voluntary accommodation. Those 100 entities will not need to file additional self-certifications or notices. HHS also assumes that an additional 9 entities that were not using the previous accommodation will opt into it. Those entities will be subject to the self-certification or notice requirement.

In order to estimate the cost for an entity that chooses to opt into the accommodation process, HHS assumes, as it did in its August 2014 interim final rules, that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS.[99] HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 50 minutes (30 minutes of clerical labor at a cost of $55.68 per hour,[100] 10 minutes for a compensation and benefits manager at a cost of $122.02 per hour,[101] 5 minutes for legal counsel at a cost of $134.50 per hour,[102] and 5 minutes by a senior executive at a cost of $186.88 per hour [103]) preparing and sending the self-certification or notice to HHS and filing it to meet the recordkeeping requirement. Therefore, the total annual burden for preparing and providing the information in the self-certification or notice to HHS will require approximately 50 minutes for each eligible organization with an equivalent cost burden of approximately $74.96 for a total hour burden of approximately 7.5 hours with an equivalent cost of approximately $675 for 9 entities. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for approximately 3.75 burden hours with an equivalent cost of approximately $337.

HHS estimates that each self-certification or notice to HHS will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each self-certification or notice sent via mail will be $0.54. For purposes of this analysis, HHS assumes that 50 percent of self-certifications or notices to HHS will be mailed. The total cost for sending the self-certifications or notices to HHS by mail is approximately $2.70 for 5 entities. As DOL and HHS share jurisdiction they are splitting the cost burden so each will account for $1.35 of the cost burden.

b. ICRs Regarding Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(e))

As required by the July 2015 final regulations, a health insurance issuer or third party administrator providing or arranging separate payments for contraceptive services for participants and beneficiaries in insured or self-insured group health plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations is required to provide a written notice to plan participants and beneficiaries (or student enrollees and covered dependents) informing them of the availability of such payments. The notice must be separate from, but contemporaneous with (to the extent possible), any application materials distributed in connection with enrollment (or re-enrollment) in group or student coverage of the eligible organization in any plan year to which the accommodation is to apply and will be provided annually. To satisfy the notice requirement, issuers and third party administrators may, but are not required to, use the model language set forth previously by HHS or substantially similar language. The burden for this ICR is currently approved under OMB control number 0938–1292.

As mentioned, HHS is anticipating that approximately 109 entities will use the optional accommodation (100 that used it previously, and 9 that will newly opt into it). It is unknown how many issuers or third party administrators provide health insurance coverage or services in connection with health plans of eligible organizations, but HHS will assume at least 109. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at $55.68 per hour) [104] and 15 minutes of management review (at $117.40 per hour) [105] to prepare the notices. The total burden for each issuer or third party administrator to prepare notices will be 1.25 hours with an equivalent cost of approximately $85.03. The total burden for all issuers or third party administrators will be 136 hours, with an equivalent cost of $9,268. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 68 burden hours with an equivalent cost of $4,634, with approximately 55 respondents.

As discussed above, the Departments estimate that 770,000 persons will be covered in the plans of the 100 entities that previously used the accommodation and will continue doing so, and that an additional 9 entities will newly opt into the accommodation. It is not known how many persons will be covered in the plans of the 9 entities newly using the accommodation. Assuming that those 9 entities will have a similar number of covered persons per entity, we estimate that all 109 accommodated entities will encompass 839,300 covered persons. We assume that sending one notice to each participant will satisfy the need to send the notices to all participants and dependents. Among persons covered by plans, approximately 50.1 percent are participants and 49.9 percent are

[99] For purposes of this analysis, the Department assumes that the same amount of time will be required to prepare the self-certification and the notice to HHS.

[100] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84, *https://www.bls.gov/oes/current/oes436011.htm*.

[101] Occupation code 11–3111 for Compensation and Benefits Managers with mean hourly wage $61.01, *https://www.bls.gov/oes/current/oes113111.htm*.

[102] Occupation code 23–1011 for Lawyers with mean hourly wage $67.25, *https://www.bls.gov/oes/current/oes231011.htm*.

[103] Occupation code11–1011 for Chief Executives with mean hourly wage $93.44, *https://www.bls.gov/oes/current/oes111011.htm*.

[104] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84.

[105] Occupation code 11–1021 General and Operations Managers with mean hourly wage $58.70.

dependents.[106] For 109 entities, the total number of notices will be 420,490. For purposes of this analysis, the Departments also assume that 53.7 percent of notices will be sent electronically, and 46.3 percent will be mailed.[107] Therefore, approximately 194,687 notices will be mailed. HHS estimates that each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54. The total cost for sending approximately 194,687 notices by mail is approximately $105,131. As DOL and HHS share jurisdiction, they are splitting the cost burden so each will account for $52,565 of the cost burden.

c. ICRs Regarding Notice of Revocation of Accommodation (§ 147.131(c)(4))

An eligible organization may revoke its use of the accommodation process; its issuer or third party administrator must provide written notice of such revocation to participants and beneficiaries as soon as practicable. As discussed above, HHS estimates that 109 entities that are using the accommodation process will revoke their use of the accommodation, and will therefore be required to cause the notification to be sent (the issuer or third party administrator can send the notice on behalf of the entity). For the purpose of calculating ICRs associated with revocations of the accommodation, and for various reasons discussed above, HHS assumes that litigating entities that were previously using the accommodation and that will revoke it fall within the estimated 109 entities that will revoke the accommodation overall.

As before, HHS assumes that, for each issuer or third party administrator, a manager and inside legal counsel and clerical staff will need approximately 2 hours to prepare and send the notification to participants and beneficiaries and maintain records (30 minutes for a manager at a cost of $117.40 per hour,[108] 30 minutes for legal counsel at a cost of $134.50 per hour [109], 1 hour for clerical labor at a cost of $55.68 per hour [110]). The burden per respondent will be 2 hours with an equivalent cost of $181.63; for 109 entities, the total burden will be 218 hours with an equivalent cost of approximately $19,798. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 109 burden hours with an equivalent cost of approximately $9,899.

As discussed above, HHS estimates that there are 257,000 covered persons in accommodated plans that will revoke their accommodated status and use the expanded exemption.[111] As before, we use the average of 50.1 percent of covered persons who are policyholders, and estimate that an average of 53.7 percent of notices will be sent electronically and 46.3 percent by mail. Therefore, approximately 128,757 notices will be sent, of which 59,615 notices will be mailed. HHS estimates that each notice will require $0.49 in postage and $0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be $0.54. The total cost for sending approximately 59,615 notices by mail is approximately $32,192. As DOL and HHS share jurisdiction, they are splitting the hour burden so each will account for 64,379 notices, with an equivalent cost of approximately $16,096.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section	OMB control No.	Number of respondents	Responses	Burden per respondent (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total cost ($)
Self-Certification or Notices to HHS	0938—NEW	*5	5	0.83	3.75	$89.95	$337.31	$338.66
Notice of Availability of Separate Payments for Contraceptive Services.	0938—NEW	*55	210,245	1.25	68.13	68.02	4,634.14	57,199.59
Notice of Revocation of Accommodation	0938—NEW	*55	64,379	2.00	109	90.82	9,898.84	25,994.75
Total		*115	274,629	4.08	180.88		14,870.29	83,533.00

*The total number of respondents is 227 (= 9+109+109) for both HHS and DOL, but the summaries here and below exceed that total because of rounding up that occurs when sharing the burden between HHS and DOL.

Note: There are no capital/maintenance costs associated with the ICRs contained in this rule; therefore, we have removed the associated column from Table 1. Postage and material costs are included in Total Cost.

We are soliciting comments on all of the information collection requirements contained in these interim final rules. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938–1292 and 0938–1248. HHS is requesting a new OMB control number that will ultimately contain the approval for the new information collection requirements contained in these interim

[106] "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[107] According to data from the National Telecommunications and Information Agency (NTIA), 36.0 percent of individuals age 25 and over have access to the Internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out that are automatically enrolled (for a total of 30.2 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 38.5 percent of individuals age 25 and over have access to the Internet outside of work. According to a Pew Research Center survey, 61 percent of Internet users use online banking, which is used as the proxy for the number of Internet users who will opt in for electronic disclosure (for a total of 23.5 percent receiving electronic disclosure outside of work). Combining the 30.2 percent who receive electronic disclosure at work with the 23.5 percent who receive electronic disclosure outside of work produces a total of 53.7 percent who will receive electronic disclosure overall.

[108] Occupation code 11–1021 for General and Operations Managers with mean hourly wage $58.70. *https://www.bls.gov/oes/current/oes111021.htm.*

[109] Occupation code 23–1011 for Lawyers with mean hourly wage $67.25. *https://www.bls.gov/oes/current/oes231011.htm.*

[110] Occupation code 43–6011 for Executive Secretaries and Executive Administrative Assistants with mean hourly wage $27.84. *https://www.bls.gov/oes/current/oes436011.htm.*

[111] In estimating the number of women that might have their contraceptive coverage affected by the expanded exemption, we indicated that we do not know the extent to which the number of women in accommodated plans affected by these rules overlap with the number of women in plans offered by litigating entities that will be affected by these rules, though we assume there is significant overlap. That uncertainty should not affect the calculation of the ICRs for revocation notices, however. If the two numbers overlap, the estimates of plans revoking the accommodation and policyholders covered in those plans would already include plans and policyholders of litigating entities. If the numbers do not overlap, those litigating entity plans would not presently be enrolled in the accommodation, and therefore would not need to send notices concerning revocation of accommodated status.

final rules as well as the related requirements currently approved under 0938–1292 and 0938–1248. In an effort to consolidate the number of information collection requests, we will formally discontinue the control numbers 0938–1292 and 0938–1248 once the new information collection request associated with these interim final rules is approved.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of these interim final rules with comment period.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov.* PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

These interim final rules amend the ICR by changing the accommodation process to an optional process for exempt organizations and requiring a notice of revocation to be sent by the issuer or third party administrator to participants and beneficiaries in plans whose employer who revokes their accommodation. DOL submitted the ICRs in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. In an effort to consolidate the number of information collection requests, DOL will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once the ICR is approved DOL will discontinue 1210–0152. A copy of the information collection request may be obtained free of charge on the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001.* This approval will allow respondents to temporarily utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden.

Consistent with the analysis in the HHS PRA section above, the Departments expect that each of the estimated 9 eligible organizations newly opting into the accommodation will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to self-certify or notify HHS. Each of the 109 issuers or third party administrators for the 109 eligible organizations that make use of the accommodation overall will distribute Notices of Availability of Separate Payments for Contraceptive Services. These issuers and third party administrators will spend approximately 1.25 hours in preparation time and incur $0.54 cost per mailed notice. Notices of Availability of Separate Payments for Contraceptive Services will need to be sent to 420,489 policyholders, and 53.7 percent of the notices will be sent electronically, while 46.3 percent will be mailed. Finally, 109 entities using the previous accommodation process will revoke its use and will therefore be required to cause the Notice of Revocation of Accommodation to be sent (the issuer or third party administrator can send the notice on behalf of the entity). These entities will spend approximately two hours in preparation time and incur $0.54 cost per mailed notice. Notice of Revocation of Accommodation will need to be sent to an average of 128,757 policyholders and 53.7 percent of the notices will be sent electronically. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection.
Agency: DOL–EBSA.
Title: Coverage of Certain Preventive Services under the Affordable Care Act—Private Sector.
OMB Numbers: 1210–0150.
Affected Public: Private Sector—Not for profit and religious organizations; businesses or other for-profits.
Total Respondents: 114 [112] (combined with HHS total is 227).
Total Responses: 274,628 (combined with HHS total is 549,255).
Frequency of Response: On occasion.
Estimated Total Annual Burden Hours: 181 (combined with HHS total is 362 hours).
Estimated Total Annual Burden Cost: $68,662 (combined with HHS total is $137,325).
Type of Review: Revised Collection.
Agency: DOL–EBSA.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, "[t]o the maximum extent permitted by law, the Secretary of the Department of Health and Human Services and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." In addition, agencies are directed to "take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market." These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act, RFRA, and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting

[112] Denotes that there is an overlap between jurisdiction shared by HHS and DOL over these respondents and therefore they are included only once in the total.

costs.[113] Therefore, this interim final rule is considered an Executive Order 13771 deregulatory action.

F. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflater for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.

G. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VII. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Public Law 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ 2. Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(1) *In general.* [Reserved]. For further guidance, see § 54.9815–2713T(a)(1) introductory text.

* * * * *

(iv) [Reserved]. For further guidance, see § 54.9815–2713T(a)(1)(iv).

* * * * *

■ 3. Section 54.9815–2713T is added to read as follows:

§ 54.9815–2713T Coverage of preventive health services (temporary).

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of § 54.9815–2713 and subject to § 54.9815–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i)–(iii) [Reserved]. For further guidance, see § 54.9815–2713(a)(1)(i) through (iii).

[113] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of § 54.9815–2713 as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

(2)–(c) [Reserved]. For further guidance, see § 54.9815–2713(a)(2) through (c).

(d) *Effective/Applicability date.* (1) Paragraphs (a) through (c) of this section are applicable beginning on April 16, 2012, except—

(2) Paragraphs (a)(1) introductory text and (a)(1)(iv) of this section are effective on October 6, 2017.

(e) *Expiration date.* This section expires on October 6, 2020.

■ 4. Section 54.9815–2713A is revised to read as follows:

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

(a) through (f) [Reserved]. For further guidance, see § 54.9815–2713AT.

(b)

■ 5. Section 54.9815–2713AT is added to read as follows:

§ 54.9815–2713AT Accommodations in connection with coverage of preventive health services (temporary).

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its status under paragraph (a)(1) of this section and under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary of Labor or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give sixty-days notice pursuant to section 2715(d)(4) of the PHS Act and § 54.9815–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(6) Where an otherwise eligible organization is an ERISA-exempt church plan within the meaning of section 3(33) of ERISA and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The third party administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, provide or arrange payments for contraceptive services in accordance with paragraphs (b)(2)(i) or (ii) of this section, and receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process—

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 54.9815–2713.

(B) When a notice is provided to the Secretary of the Department Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Department Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815 of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group

health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): "Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer]."

(e) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 54.9815–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

(g) *Expiration date.* This section expires on October 6, 2020.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 6. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

■ 7. Section 2590.715–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) *Services.*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 2590.715–2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to 45 CFR 147.131 and 147.132.

* * * * *

■ 8. Section 2590.715–2713A is revised to read as follows:

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (a)(1) through (4) of this section.

(1) The organization is an objecting entity described in 45 CFR 147.132(a)(1)(i) or (ii);

(2) Notwithstanding its exempt status under 45 CFR 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (b) or (c) of this section as applicable; and

(3) [Reserved]

(4) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary of the Department of Health and Human Services as described in paragraph (b) or (c) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(5) An eligible organization may revoke its use of the accommodation process, and its issuer or third party administrator must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer or third party administrator through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to PHS Act section 2715(d)(4) and § 2590.715–2715(b), if applicable, to revoke its use of the accommodation process.

(b) *Optional accommodation—self-insured group health plans.* (1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis may voluntarily elect an optional accommodation under which its third party administrator(s) will provide or arrange payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more third party administrators.

(ii) The eligible organization must provide either a copy of the self-certification to each third party administrator or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in § 2510.3–16 of this chapter and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable), but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's third party administrators. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation process to remain in effect. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan's third party administrators informing the third party administrator that the Secretary of the Department of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under § 2510.3–16 of this chapter and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section, and is willing to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, then the third party administrator will provide or arrange payments for contraceptive services, using one of the following methods—

(i) Provide payments for the contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(5) Where an otherwise eligible organization does not contract with a third party administrator and it files a self-certification or notice under paragraph (b)(1)(ii) of this section, the obligations under paragraph (b)(2) of this section do not apply, and the otherwise eligible organization is under no requirement to provide coverage or payments for contraceptive services to which it objects. The plan administrator for that otherwise eligible organization may, if it and the otherwise eligible organization choose, arrange for payments for contraceptive services from an issuer or other entity in accordance with paragraph (b)(2)(ii) of this section, and such issuer or other entity may receive reimbursements in accordance with paragraph (b)(3) of this section.

(c) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in 45 CFR 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715–2713.

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in 45 CFR 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of Department Health and Human Services for the optional accommodation process to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(2)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (c)(2)(ii) of this section and does not have its own objection as described in 45 CFR 147.132 to providing the contraceptive services to which the eligible organization objects, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv) for plan participants and beneficiaries

for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 715 of ERISA. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 2590.715–2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (c)(1)(ii) of this section.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the optional accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides or arranges separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): "Your employer has certified that your group health plan qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer]."

(e) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 2590.715–2713(a)(1)(iv).

(f) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 9. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 10. Section 147.130 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131 and 147.132, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

* * * * *

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131 and 147.132.

* * * * *

■ 11. Section 147.131 is revised to read as follows:

§ 147.131 Accommodations in connection with coverage of certain preventive health services.

(a)–(b) [Reserved]

(c) *Eligible organizations for optional accommodation.* An eligible organization is an organization that meets the criteria of paragraphs (c)(1) through (3) of this section.

(1) The organization is an objecting entity described in § 147.132(a)(1)(i) or (ii).

(2) Notwithstanding its exempt status under § 147.132(a), the organization voluntarily seeks to be considered an eligible organization to invoke the optional accommodation under paragraph (d) of this section; and

(3) The organization self-certifies in the form and manner specified by the Secretary or provides notice to the Secretary as described in paragraph (d) of this section. To qualify as an eligible organization, the organization must make such self-certification or notice available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (d) of this section applies. The self-certification or notice must be executed by a person authorized to make the certification or provide the notice on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(4) An eligible organization may revoke its use of the accommodation process, and its issuer must provide participants and beneficiaries written notice of such revocation as specified in guidance issued by the Secretary of the Department of Health and Human Services. If contraceptive coverage is currently being offered by an issuer through the accommodation process, the revocation will be effective on the first day of the first plan year that begins on or after 30 days after the date of the revocation (to allow for the provision of notice to plan participants in cases where contraceptive benefits will no longer be provided). Alternatively, an eligible organization may give 60-days notice pursuant to section 2715(d)(4) of the PHS Act and § 147.200(b), if applicable, to revoke its use of the accommodation process.

(d) *Optional accommodation—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers may voluntarily elect an optional accommodation under which its health insurance issuer(s) will provide payments for all or a subset of contraceptive services for one or more plan years. To invoke the optional accommodation process:

(i) The eligible organization or its plan must contract with one or more health insurance issuers.

(ii) The eligible organization must provide either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of the Department of Health and Human Services that it is an eligible organization and of its objection as described in § 147.132 to coverage for all or a subset of contraceptive services.

(A) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130(a)(iv).

(B) When a notice is provided to the Secretary of the Department of Health and Human Services, the notice must include the name of the eligible organization; a statement that it objects as described in § 147.132 to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable) but that it would like to elect the optional accommodation process; the plan name and type (that is, whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of section 3(33) of ERISA); and the name and contact information for any of the plan's health insurance issuers. If there is a change in any of the information required to be included in the notice, the eligible organization must provide updated information to the Secretary of the Department of Health and Human Services for the optional accommodation to remain in effect. The Department of Health and Human Services will send a separate notification to each of the plan's health insurance issuers informing the issuer that the Secretary of the Deparement of Health and Human Services has received a notice under paragraph (d)(1)(ii) of this section and describing the obligations of the issuer under this section.

(2) If an issuer receives a copy of the self-certification from an eligible organization or the notification from the Department of Health and Human Services as described in paragraph (d)(1)(ii) of this section and does not have an objection as described in § 147.132 to providing the contraceptive services identified in the self-certification or the notification from the Department of Health and Human Services, then the issuer will provide payments for contraceptive services as follows—

(i) The issuer must expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan and provide separate payments for any contraceptive services required to be covered under § 141.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(3) A health insurance issuer may not require any documentation other than a copy of the self-certification from the eligible organization or the notification from the Department of Health and Human Services described in paragraph (d)(1)(ii) of this section.

(e) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the optional accommodation in paragraph (d) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (d) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (e) "Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the Federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments . If you have any questions about this notice, contact [contact information for health insurance issuer]."

(f) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(g) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

■ 12. Add § 147.132 to read as follows:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(c) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[FR Doc. 2017–21851 Filed 10–6–17; 11:15 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD–9828]

RIN 1545–BN91

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB84

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9925–IFC]

RIN 0938–AT46

Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: The United States has a long history of providing conscience protections in the regulation of health care for entities and individuals with objections based on religious beliefs or moral convictions. These interim final rules expand exemptions to protect moral convictions for certain entities and individuals whose health plans are subject to a mandate of contraceptive coverage through guidance issued pursuant to the Patient Protection and Affordable Care Act. These rules do not alter the discretion of the Health Resources and Services Administration, a component of the United States Department of Health and Human Services, to maintain the guidelines requiring contraceptive coverage where no regulatorily recognized objection exists. These rules also provide certain morally objecting entities access to the voluntary "accommodation" process regarding such coverage. These rules do not alter multiple other Federal programs that provide free or subsidized contraceptives for women at risk of unintended pregnancy.

DATES:

Effective date: These interim final rules are effective on October 6, 2017.

Comment date: Written comments on these interim final rules are invited and must be received by December 5, 2017.

ADDRESSES: Written comments may be submitted to the Department of Health and Human Services as specified below. Any comment that is submitted will be shared with the Department of Labor and the Department of the Treasury, and will also be made available to the public.

Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously. Comments, identified by "Preventive Services," may be submitted one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9925–IFC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9925–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Comments received will be posted without change to *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jeff Wu (310) 492–4305 or *marketreform@cms.hhs.gov* for Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), Amber Rivers or Matthew Litton, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317–5500.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*www.dol.gov/ebsa*). Information from HHS on private health insurance coverage can be found on CMS's Web site (*www.cms.gov/cciio*), and information on health care reform can be found at *www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the context of legal requirements touching on certain sensitive health care issues—including health coverage of contraceptives—Congress has a consistent history of supporting conscience protections for moral convictions alongside protections for religious beliefs, including as part of its efforts to promote access to health services.[1] Against that backdrop,

[1] *See, for example,* 42 U.S.C. 300a–7 (protecting individuals and health care entities from being required to provide or assist sterilizations, abortions, or other lawful health services if it would violate their "religious beliefs or moral convictions"); 42 U.S.C. 238n (protecting individuals and entities that object to abortion); Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d) (Departments of Labor, HHS,

Congress granted the Health Resources and Services Administration (HRSA), a component of the United States Department of Health and Human Services (HHS), discretion under the Patient Protection and Affordable Care Act to specify that certain group health plans and health insurance issuers shall cover, "with respect to women, such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by" HRSA (the "Guidelines"). Public Health Service Act section 2713(a)(4). HRSA exercised that discretion under the last Administration to require health coverage for, among other things, certain contraceptive services,[2] while the administering agencies—the Departments of Health and Human Services, Labor, and the Treasury (collectively, "the Departments"),[3] exercised both the discretion granted to HHS through HRSA, its component, in PHS Act section 2713(a)(4), and the authority granted to the Departments as administering agencies (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92) to issue regulations to guide HRSA in carrying out that provision. Through rulemaking, including three interim final rules, the Departments exempted and accommodated certain religious objectors, but did not offer an exemption or accommodation to any group possessing non-religious moral objections to providing coverage for some or all contraceptives. Many individuals and entities challenged the contraceptive coverage requirement and regulations (hereinafter, the "contraceptive Mandate," or the "Mandate") as being inconsistent with various legal protections. These challenges included lawsuits brought by some non-religious organizations with sincerely held moral convictions inconsistent with providing coverage for some or all contraceptive services, and those cases continue to this day. Various public comments were also submitted asking the Departments to protect objections based on moral convictions.

The Departments have recently exercised our discretion to reevaluate these exemptions and accommodations. This evaluation includes consideration of various factors, such as: The interests served by the existing Guidelines, regulations, and accommodation process;[4] the extensive litigation; Executive Order 13798, "Promoting Free Speech and Religious Liberty" (May 4, 2017); Congress' history of providing protections for moral convictions alongside religious beliefs regarding certain health services (including contraception, sterilization, and items or services believed to involve abortion); the discretion afforded under PHS Act section 2713(a)(4); the structure and intent of that provision in the broader context of section 2713 and the Patient Protection and Affordable Care Act; and the history of the regulatory process and comments submitted in various requests for public comments (including in the Departments' 2016 Request for Information). Elsewhere in this issue of the **Federal Register**, the Departments published, contemporaneously with these interim final rules, companion interim final rules expanding exemptions to protect sincerely held religious beliefs in the context of the contraceptive Mandate.

In light of these considerations, the Departments issue these interim final rules to better balance the Government's interest in promoting coverage for contraceptive and sterilization services with the Government's interests in providing conscience protections for individuals and entities with sincerely held moral convictions in certain health care contexts, and in minimizing burdens imposed by our regulation of the health insurance market.

A. The Affordable Care Act

Collectively, the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010, are known as the Affordable Care Act. In signing the Affordable Care Act, President Obama issued Executive Order 13535 (March 24, 2010), which declared that, "[u]nder the Act, longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact" and that "[n]umerous executive agencies have a role in ensuring that these restrictions are enforced, including the Department of Health and Human Services (HHS)." Those laws protect objections based on moral convictions in addition to religious beliefs.

The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. In addition, the Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and thereby make them applicable to certain group health plans regulated under ERISA or the Code. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728 of the PHS Act.

These interim final rules concern section 2713 of the PHS Act. Where it applies, section 2713(a)(4) of the PHS

and Education, and Related Agencies Appropriations Act), Public Law 115–31 (protecting any "health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan" in objecting to abortion for any reason); *Id.* at Div. C, Title VIII, Sec. 808 (regarding any requirement of "the provision of contraceptive coverage by health insurance plans" in the District of Columbia, "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions."); *Id.* at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act) (protecting individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions"); *Id.* at Div. I, Title III (Department of State, Foreign Operations, and Related Programs Appropriations Act) (protecting applicants for family planning funds based on their "religious or conscientious commitment to offer only natural family planning"); 42 U.S.C. 290bb–36 (prohibiting the statutory section from being construed to require suicide related treatment services for youth where the parents or legal guardians object based on "religious beliefs or moral objections"); 42 U.S.C. 1395w–22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396a(w)(3) (ensuring particular Federal law does not infringe on "conscience" as protected in State law concerning advance directives); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 2996f(b) (protecting objection to abortion funding in legal services assistance grants based on "religious beliefs or moral convictions"); 42 U.S.C. 14406 (protecting organizations and health providers from being required to inform or counsel persons pertaining to assisted suicide); 42 U.S.C. 18023 (blocking any requirement that issuers or exchanges must cover abortion); 42 U.S.C. 18113 (protecting health plans or health providers from being required to provide an item or service that helps cause assisted suicide); *see also* 8 U.S.C. 1182(g) (protecting vaccination objections by "aliens" due to "religious beliefs or moral convictions"); 18 U.S.C. 3597 (protecting objectors to participation in Federal executions based on "moral or religious convictions"); 20 U.S.C. 1688 (prohibiting sex discrimination law to be used to require assistance in abortion for any reason); 22 U.S.C. 7631(d) (protecting entities from being required to use HIV/AIDS funds contrary to their "religious or moral objection").

[2] This document's references to "contraception," "contraceptive," "contraceptive coverage," or "contraceptive services" generally includes contraceptives, sterilization, and related patient education and counseling, unless otherwise indicated.

[3] Note, however, that in sections under headings listing only two of the three Departments, the term "Departments" generally refers only to the two Departments listed in the heading.

[4] In this IFR, we generally use "accommodation" and "accommodation process" interchangeably.

Act requires coverage without cost sharing for "such additional" women's preventive care and screenings "as provided for" and "supported by" guidelines developed by HRSA/HHS. The Congress did not specify any particular additional preventive care and screenings with respect to women that HRSA could or should include in its Guidelines, nor did Congress indicate whether the Guidelines should include contraception and sterilization.

The Departments have consistently interpreted section 2713(a)(4)'s of the PHS Act grant of authority to include broad discretion to decide the extent to which HRSA will provide for and support the coverage of additional women's preventive care and screenings in the Guidelines. In turn, the Departments have interpreted that discretion to include the ability to exempt entities from coverage requirements announced in HRSA's Guidelines. That interpretation is rooted in the text of section 2713(a)(4) of the PHS Act, which allows HRSA to decide the extent to which the Guidelines will provide for and support the coverage of additional women's preventive care and screenings.

Accordingly, the Departments have consistently interpreted section 2713(a)(4) of the PHS Act reference to "comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph" to grant HRSA authority to develop such Guidelines. And because the text refers to Guidelines "supported by the Health Resources and Services Administration for purposes of this paragraph," the Departments have consistently interpreted that authority to afford HRSA broad discretion to consider the requirements of coverage and cost-sharing in determining the nature and extent of preventive care and screenings recommended in the guidelines. (76 FR 46623). As the Departments have noted, these Guidelines are different from "the other guidelines referenced in section 2713(a), which pre-dated the Affordable Care Act and were originally issued for purposes of identifying the non-binding recommended care that providers should provide to patients." *Id.* Guidelines developed as nonbinding recommendations for care implicate significantly different legal and policy concerns than guidelines developed for a mandatory coverage requirement. To guide HRSA in exercising the discretion afforded to it in section 2713(a)(4), the Departments have previously promulgated regulations defining the scope of permissible religious exemptions and accommodations for such guidelines. (45 CFR 147.131). The interim final rules set forth herein are a necessary and appropriate exercise of the authority delegated to the Departments as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Our interpretation of section 2713(a)(4) of the PHS Act is confirmed by the Affordable Care Act's statutory structure. The Congress did not intend to require entirely uniform coverage of preventive services. (76 FR 46623). To the contrary, Congress carved out an exemption from section 2713 for grandfathered plans. This exemption is not applicable to many of the other provisions in Title I of the Affordable Care Act—provisions previously referred to by the Departments as providing "particularly significant protections." (75 FR 34540). Those provisions include: Section 2704, which prohibits preexisting condition exclusions or other discrimination based on health status in group health coverage; section 2708, which prohibits excessive waiting periods (as of January 1, 2014); section 2711, which relates to lifetime limits; section 2712, which prohibits rescissions of health insurance coverage; section 2714, which extends dependent coverage until age 26; and section 2718, which imposes a medical loss ratio on health insurance issuers in the individual and group markets (for insured coverage), or requires them to provide rebates to policyholders. (75 FR 34538, 34540, 34542). Consequently, of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans not subject to section 2713 of the PHS Act.[5] As the Supreme Court observed, "there is no legal requirement that grandfathered plans ever be phased out." *Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2764 n.10 (2014).

The Departments' interpretation of section 2713(a)(4) of the PHS Act to permit HRSA to establish exemptions from the Guidelines, and of the Departments' own authority as administering agencies to guide HRSA in establishing such exemptions, is also consistent with Executive Order 13535. That order, issued upon the signing of the Affordable Care Act, specified that "longstanding Federal laws to protect conscience . . . remain intact," including laws that protect religious beliefs and moral convictions from certain requirements in the health care context. Although the text of Executive Order 13535 does not require the expanded exemptions issued in these interim final rules, the expanded exemptions are, as explained below, consistent with longstanding Federal laws to protect conscience regarding certain health matters, and are consistent with the intent that the Affordable Care Act would be implemented in consideration of the protections set forth in those laws.

B. The Regulations Concerning Women's Preventive Services

On July 19, 2010, the Departments issued interim final rules implementing section 2713 of the PHS Act (75 FR 41726). Those interim final rules charged HRSA with developing the Guidelines authorized by section 2713(a)(4) of the PHS Act.

1. The Institute of Medicine Report

In developing the Guidelines, HRSA relied on an independent report from the Institute of Medicine (IOM, now known as the National Academy of Medicine) on women's preventive services, issued on July 19, 2011, "Clinical Preventive Services for Women, Closing the Gaps" (IOM 2011). The IOM's report was funded by the HHS Office of the Assistant Secretary for Planning and Evaluation, pursuant to a funding opportunity that charged the IOM to conduct a review of effective preventive services to ensure women's health and well-being.[6]

The IOM made a number of recommendations with respect to women's preventive services. As relevant here, the IOM recommended that the Guidelines cover the full range of Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. Because FDA includes in the category of "contraceptives" certain drugs and devices that may not only prevent conception (fertilization), but may also prevent implantation of an embryo,[7] the IOM's recommendation included

[5] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

[6] Because section 2713(a)(4) of the PHS Act specifies that the HRSA Guidelines shall include preventive care and screenings "with respect to women," the Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

[7] FDA's guide "Birth Control: Medicines To Help You," specifies that various approved contraceptives, including Levonorgestrel, Ulipristal Acetate, and IUDs, work mainly by preventing fertilization and "may also work . . . by preventing attachment (implantation) to the womb (uterus)" of a human embryo after fertilization. Available at *https://www.fda.gov/forconsumers/byaudience/forwomen/freepublications/ucm313215.htm.*

several contraceptive methods that many persons and organizations believe are abortifacient—that is, as causing early abortion—and which they conscientiously oppose for that reason distinct from whether they also oppose contraception or sterilization. One of the 16 members of the IOM committee, Dr. Anthony LoSasso, a Professor at the University of Illinois at Chicago School of Public Health, wrote a formal dissenting opinion. He stated that the IOM committee did not have sufficient time to evaluate fully the evidence on whether the use of preventive services beyond those encompassed by section 2713(a)(1) through (3) of the PHS Act leads to lower rates of disability or disease and increased rates of well-being, such that the IOM should recommend additional services to be included under Guidelines issued under section 2713(a)(4) of the PHS Act. He further stated that "the recommendations were made without high quality, systematic evidence of the preventive nature of the services considered," and that "the committee process for evaluation of the evidence lacked transparency and was largely subject to the preferences of the committee's composition. Troublingly, the process tended to result in a mix of objective and subjective determinations filtered through a lens of advocacy." He also raised concerns that the committee did not have time to develop a framework for determining whether coverage of any given preventive service leads to a reduction in healthcare expenditure.[8] IOM 2011 at 231–32. In its response to Dr. LoSasso, the other 15 committee members stated in part that "At the first committee meeting, it was agreed that cost considerations were outside the scope of the charge, and that the committee should not attempt to duplicate the disparate review processes used by other bodies, such as the USPSTF, ACIP, and Bright Futures. HHS, with input from this committee, may consider other factors including cost in its development of coverage decisions."

2. HRSA's 2011 Guidelines and the Departments' Second Interim Final Rules

On August 1, 2011, HRSA released onto its Web site its Guidelines for women's preventive services, adopting the recommendations of the IOM. *https://www.hrsa.gov/womensguidelines/* The Guidelines included coverage for all FDA-approved contraceptives, sterilization procedures, and related patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (hereinafter "the Mandate").

In administering this Mandate, on August 1, 2011, the Departments promulgated interim final rules amending our 2010 interim final rules. (76 FR 46621) (2011 interim final rules). The 2011 interim final rules specified that HRSA has the authority to establish exemptions from the contraceptive coverage requirement for certain group health plans established or maintained by certain religious employers and for health insurance coverage provided in connection with such plans.[9] The 2011 interim final rules only offered the exemption to a narrow scope of employers, and only if they were religious. As the basis for adopting that limited definition of religious employer, the 2011 interim final rules stated that they relied on the laws of some "States that exempt certain religious employers from having to comply with State law requirements to cover contraceptive services." (76 FR 46623). Several comments were submitted asking that the exemption include those who object to contraceptive coverage based on non-religious moral convictions, including pro-life, non-profit advocacy organizations.[10]

3. The Departments' Subsequent Rulemaking on the Accommodation and Third Interim Final Rules

Final regulations issued on February 10, 2012, adopted the definition of "religious employer" in the 2011 interim final rules without modification (2012 final regulations).[11] (77 FR 8725). The exemption did not require exempt employers to file any certification form or comply with any other information collection process.

Contemporaneously with the issuance of the 2012 final regulations, HHS—with the agreement of the Department of Labor (DOL) and the Department of the Treasury—issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments with respect to group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and the group health insurance coverage provided in connection with such plans).[12] The temporary safe harbor did not include nonprofit organizations that had an objection to contraceptives based on moral convictions but not religious beliefs, nor did it include for-profit entities of any kind. The Departments stated that, during the temporary safe harbor, the Departments would engage in rulemaking to achieve "two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, nonprofit organizations' religious objections to covering contraceptive services." (77 FR 8727).

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described possible approaches to achieve those goals with respect to religious nonprofit organizations, and solicited public comments on the same. (77 FR 16501). Following review of the comments on the ANPRM, the Departments published proposed regulations on February 6, 2013 (2013 NPRM) (78 FR 8456).

The 2013 NPRM proposed to expand the definition of "religious employer" for purposes of the religious employer exemption. Specifically, it proposed to require only that the religious employer be organized and operate as a nonprofit entity and be referred to in section 6033(a)(3)(A)(i) or (iii) of the Code, eliminating the requirements that a religious employer—(1) have the inculcation of religious values as its purpose; (2) primarily employ persons who share its religious tenets; and (3) primarily serve persons who share its religious tenets. The proposed expanded

[8] The Departments do not relay these dissenting remarks as an endorsement of the remarks, but to describe the history of the Guidelines, which includes this part of the report that IOM provided to HRSA.

[9] The 2011 amended interim final rules were issued and effective on August 1, 2011, and published in the **Federal Register** on August 3, 2011. (76 FR 46621).

[10] *See, for example,* Americans United for Life ("AUL") Comment on CMA–9992–IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496.*

[11] The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

[12] Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: *http://www.lb7.uscourts.gov/documents/12cv3932.pdf.* The guidance, as reissued on August 15, 2012, clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See final rule entitled "Student Health Insurance Coverage" published March 21, 2012 (77 FR 16457).

definition still encompassed only religious entities.

The 2013 NPRM also proposed to create a compliance process, which it called an accommodation, for group health plans established, maintained, or arranged by certain eligible nonprofit organizations that fell outside the houses of worship and integrated auxiliaries covered by section 6033(a)(3)(A)(i) or (iii) of the Code (and, thus, outside of the religious employer exemption). The 2013 NPRM proposed to define such eligible organizations as nonprofit entities that hold themselves out as religious, oppose providing coverage for certain contraceptive items on account of religious objections, and maintain a certification to this effect in their records. The 2013 NPRM stated, without citing a supporting source, that employees of eligible organizations "may be less likely than" employees of exempt houses of worship and integrated auxiliaries to share their employer's faith and opposition to contraception on religious grounds. (78 FR 8461). The 2013 NPRM therefore proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries enrolled in the eligible organization's plan—and without any cost to the eligible organization.[13] In the case of a self-insured group health plan established or maintained by an eligible organization, the 2013 NPRM presented potential approaches under which the third party administrator of the plan would provide or arrange for contraceptive coverage to plan participants and beneficiaries. The proposed accommodation process was not to be offered to non-religious nonprofit organizations, nor to any for-profit entities. Public comments again included the request that exemptions encompass objections to contraceptive coverage based on moral convictions and not just based on religious beliefs.[14] On August 15, 2012, the Departments extended our temporary safe harbor until the first plan year beginning on or after August 1, 2013.

The Departments published final regulations on July 2, 2013 (July 2013 final regulations) (78 FR 39869). The July 2013 final regulations finalized the expansion of the exemption for houses of worship and their integrated auxiliaries. Although some commenters had suggested that the exemption be further expanded, the Departments declined to adopt that approach. The July 2013 regulations stated that, because employees of objecting houses of worship and integrated auxiliaries are relatively likely to oppose contraception, exempting those organizations "does not undermine the governmental interests furthered by the contraceptive coverage requirement." (78 FR 39874). However, like the 2013 NPRM, the July 2013 regulations assumed that "[h]ouses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection" to contraceptives. *Id.*

The July 2013 regulation also finalized an accommodation for eligible organizations, which were then defined to include solely organizations that are religious. Under the accommodation, an eligible organization was required to submit a self-certification to its group health insurance issuer or third party administrator, as applicable. Upon receiving that self-certification, the issuer or third party administrator would provide or arrange for payments for the contraceptive services to the plan participants and beneficiaries enrolled in the eligible organization's plan, without requiring any cost sharing on the part of plan participants and beneficiaries and without cost to the eligible organization. With respect to self-insured plans, the third party administrators (or issuers they contracted with) could receive reimbursements by reducing user fee payments (to Federally facilitated Exchanges) by the amounts paid out for contraceptive services under the accommodation, plus an allowance for certain administrative costs, as long as the HHS Secretary requests and an authorizing exception under OMB Circular No. A–25R is in effect.[15] With respect to fully insured group health plans, the issuer was expected to bear the cost of such payments,[16] and HHS intended to clarify in guidance that the issuer could treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk corridor program calculations. The Departments extended the temporary safe harbor again on June 20, 2013, to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014.

4. Litigation Over the Mandate and the Accommodation Process

During the period when the Departments were publishing and modifying our regulations, organizations and individuals filed dozens of lawsuits challenging the Mandate. Plaintiffs included religious nonprofit organizations, businesses run by religious families, individuals, and others, including several non-religious organizations that opposed coverage of certain contraceptives under the Mandate on the basis of non-religious moral convictions. Religious for-profit entities won various court decisions leading to the Supreme Court's ruling in *Burwell* v. *Hobby Lobby Stores, Inc.* 134 S. Ct. 2751 (2014). The Supreme Court ruled against the Departments and held that, under the Religious Freedom Restoration Act of 1993 (RFRA), the Mandate could not be applied to the closely held for-profit corporations before the Court because their owners had religious objections to providing such coverage.[17]

On August 27, 2014, the Departments simultaneously issued a third set of interim final rules (August 2014 interim final rules) (79 FR 51092), and a notice of proposed rulemaking (August 2014 proposed rules) (79 FR 51118). The August 2014 interim final rules changed the accommodation process so that it could be initiated either by self-certification using EBSA Form 700 or through a notice informing the Secretary of HHS that an eligible organization had religious objections to coverage of all or a subset of contraceptive services (79 FR 51092). In response to *Hobby Lobby,* the August 2014 proposed rules extended the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage, by including them in the definition of eligible organizations (79 FR 51118). Neither the August 2014 interim final rules nor the August 2014 proposed rules extended the exemption; neither added a certification requirement for

[13] The NPRM proposed to treat student health insurance coverage arranged by eligible organizations that are institutions of higher education in a similar manner.

[14] *See, for example,* AUL Comment on CMS–9968–P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115.*

[15] *See also* 45 CFR 156.50. Under the regulations, if the third party administrator does not participate in a Federally-facilitated Exchange as an issuer, it is permitted to contract with an insurer which does so participate, in order to obtain such reimbursement. The total contraceptive user fee adjustment for the 2015 benefit year was $33 million.

[16] "[P]roviding payments for contraceptive services is cost neutral for issuers." (78 FR 39877).

[17] The Supreme Court did not decide whether RFRA would apply to publicly traded for-profit corporations. *See* 134 S. Ct. at 2774.

exempt entities; and neither encompassed objections based on non-religious moral convictions.

On July 14, 2015, the Departments finalized both the August 2014 interim final rules and the August 2014 proposed rules in a set of final regulations (the July 2015 final regulations) (80 FR 41318). (The July 2015 final regulations also encompassed issues related to other preventive services coverage.) The July 2015 final regulations allowed eligible organizations to submit a notice to HHS as an alternative to submitting the EBSA Form 700, but specified that such notice must include the eligible organization's name and an expression of its religious objection, along with the plan name, plan type, and name and contact information for any of the plan's third party administrators or health insurance issuers. The Departments indicated that such information represents the minimum information necessary for us to administer the accommodation process.

Meanwhile, a second series of legal challenges were filed by religious nonprofit organizations that stated the accommodation impermissibly burdened their religious beliefs because it utilized their health plans to provide services to which they objected on religious grounds, and it required them to submit a self-certification or notice. On November 6, 2015, the U.S. Supreme Court granted certiorari in seven similar cases under the title of a filing from the Third Circuit, *Zubik* v. *Burwell*. On May 16, 2016, the Supreme Court issued a per curiam opinion in *Zubik*, vacating the judgments of the Courts of Appeals—most of which had ruled in the Departments' favor—and remanding the cases "in light of the substantial clarification and refinement in the positions of the parties" that had been filed in supplemental briefs. 136 S. Ct. 1557, 1560 (2016). The Court stated that it anticipated that, on remand, the Courts of Appeals would "allow the parties sufficient time to resolve any outstanding issues between them." *Id.* The Court also specified that "the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice" while the cases remained pending. *Id.* at 1561.

After remand, as indicated by the Departments in court filings, meetings were held between attorneys for the Government and for the plaintiffs in those cases. The Departments also issued a Request for Information ("RFI") on July 26, 2016, seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Supreme Court's remand order. (81 FR 47741). Public comments were submitted in response to the RFI, during a comment period that closed on September 20, 2016. Those comments included the request that the exemption be expanded to include those who oppose the Mandate for either religious "or moral" reasons, consistent with various state laws (such as in Connecticut or Missouri) that protect objections to contraceptive coverage based on moral convictions.[18]

Beginning in 2015, lawsuits challenging the Mandate were also filed by various non-religious organizations with moral objections to contraceptive coverage. These organizations asserted that they believe some methods classified by FDA as contraceptives may have an abortifacient effect and therefore, in their view, are morally equivalent to abortion. These organizations have neither received an exemption from the Mandate nor do they qualify for the accommodation. For example, the organization that since 1974 has sponsored the annual March for Life in Washington, DC (March for Life), filed a complaint claiming that the Mandate violated the equal protection component of the Due Process Clause of the Fifth Amendment, and was arbitrary and capricious under the Administrative Procedure Act (APA). Citing, for example, (77 FR 8727), March for Life argued that the Departments' stated interests behind the Mandate were only advanced among women who "want" the coverage so as to prevent "unintended" pregnancy. March for Life contended that because it only hires employees who publicly advocate against abortion, including what they regard as abortifacient contraceptive items, the Departments' interests were not rationally advanced by imposing the Mandate upon it and its employees. Accordingly, March for Life contended that applying the Mandate to it (and other similarly situated organizations) lacked a rational basis and therefore doing so was arbitrary and capricious in violation of the APA. March for Life further contended that because the Departments concluded the government's interests were not undermined by exempting houses of worship and integrated auxiliaries (based on our assumption that such entities are relatively more likely than other religious nonprofits to have employees that share their views against contraception), applying the Mandate to March for Life or similar organizations that definitively hire only employees who oppose certain contraceptives lacked a rational basis and therefore violated their right of equal protection under the Due Process Clause.

March for Life's employees, who stated they were personally religious (although personal religiosity was not a condition of their employment), also sued as co-plaintiffs. They contended that the Mandate violates their rights under RFRA by making it impossible for them to obtain health insurance consistent with their religious beliefs, either from the plan March for Life wanted to offer them, or in the individual market, because the Departments offered no exemptions in either circumstance. Another non-religious nonprofit organization that opposed the Mandate's requirement to provide certain contraceptive coverage on moral grounds also filed a lawsuit challenging the Mandate. *Real Alternatives, Inc.* v. *Burwell,* 150 F. Supp. 3d 419 (M.D. Pa. 2015).

Challenges by non-religious nonprofit organizations led to conflicting opinions among the Federal courts. A district court agreed with the March for Life plaintiffs on the organization's equal protection claim and the employees' RFRA claims (not specifically ruling on the APA claim), and issued a permanent injunction against the Departments that is still in place. *March for Life* v. *Burwell.* 128 F. Supp. 3d 116 (D.D.C. 2015). The appeal in *March for Life* is pending and has been stayed since early 2016. In another case, Federal district and appellate courts in Pennsylvania disagreed with the reasoning from *March for Life* and ruled against claims brought by a similarly non-religious nonprofit employer and its religious employees. *Real Alternatives,* 150 F. Supp. 3d 419, *affirmed by* 867 F.3d 338 (3d Cir. 2017). One member of the appeals court panel in *Real Alternatives* dissented in part, stating he would have ruled in favor of the individual employee plaintiffs under RFRA. *Id.* at *18.

On December 20, 2016, HRSA updated the Guidelines via its Web site, *https://www.hrsa.gov/womensguidelines2016/index.html.* HRSA announced that, for plans subject to the Guidelines, the updated Guidelines would apply to the first plan year beginning after December 20, 2017. Among other changes, the updated Guidelines specified that the required contraceptive coverage includes follow-up care (for example, management and evaluation, as well as changes to, and removal or discontinuation of, the

[18] *See, for example, https://www.regulations.gov/document?D=CMS-2016-0123-54142; see also https://www.regulations.gov/document?D=CMS-2016-0123-54218* and *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

contraceptive method). They also specified, for the first time, that coverage should include instruction in fertility awareness-based methods for women desiring an alternative method of family planning. HRSA stated that, with the input of a committee operating under a cooperative agreement, HRSA would review and periodically update the Women's Preventive Services' Guidelines. The updated Guidelines did not alter the religious employer exemption or accommodation process, nor did they extend the exemption or accommodation process to organizations or individuals that oppose certain forms of contraception (and coverage thereof) on moral grounds.

On January 9, 2017, the Departments issued a document entitled, "FAQs About Affordable Care Act Implementation Part 36." [19] The FAQ stated that, after reviewing comments submitted in response to the 2016 RFI and considering various options, the Departments could not find a way at that time to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Departments' policy goals. The Departments did not adopt the approach requested by certain commenters, cited above, to expand the exemption to include those who oppose the Mandate for moral reasons.

On May 4, 2017, the President issued Executive Order 13798, "Promoting Free Speech and Religious Liberty." Section 3 of that order declares, "Conscience Protections with Respect to Preventive-Care Mandate. The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code."

II. Expanded Exemptions and Accommodations for Moral Convictions

These interim final rules incorporate conscience protections into the contraceptive Mandate. They do so in part to bring the Mandate into conformity with Congress's long history of providing or supporting conscience protections in the regulation of sensitive health-care issues, cognizant that Congress neither required the Departments to impose the Mandate nor prohibited them from providing conscience protections if they did so. Specifically, these interim final rules expand exemptions to the contraceptive Mandate to protect certain entities and individuals that object to coverage of some or all contraceptives based on sincerely held moral convictions but not religious beliefs, and these rules make those exempt entities eligible for accommodations concerning the same Mandate.

A. Discretion To Provide Exemptions Under Section 2713(a)(4) of the PHS Act and the Affordable Care Act

The Departments have consistently interpreted HRSA's authority under section 2713(a)(4) of the PHS Act to allow for exemptions and accommodations to the contraceptive Mandate for certain objecting organizations. Section 2713(a)(4) of the PHS Act gives HRSA discretion to decide whether and in what circumstances it will support Guidelines providing for additional women's preventive services coverage. That authority includes HRSA's discretion to include contraceptive coverage in those Guidelines, but the Congress did not specify whether or to what extent HRSA should do so. Therefore, section 2713(a)(4) of the PHS Act allows HRSA to not apply the Guidelines to certain plans of entities or individuals with religious or moral objections to contraceptive coverage, and by not applying the Guidelines to them, to exempt those entities from the Mandate. These rules are a necessary and appropriate exercise of the authority of HHS, of which HRSA is a component, and of the authority delegated to the Departments collectively as administrators of the statutes. (26 U.S.C. 9833; 29 U.S.C. 1191c; 42 U.S.C. 300gg–92).

Our protection of conscience in these interim final rules is consistent with the structure and intent of the Affordable Care Act. The Affordable Care Act refrains from applying section 2713(a)(4) of the PHS Act to millions of women in grandfathered plans. In contrast, we anticipate that conscientious exemptions to the Mandate will impact a much smaller number of women. President Obama emphasized in signing the Affordable Care Act that "longstanding Federal law to protect conscience"—laws with conscience protections encompassing moral (as well as religious) objections—specifically including (but not limited to) the Church Amendments (42 U.S.C. 300a–7), "remain intact." Executive Order 13535. Nothing in the Affordable Care Act suggests Congress' intent to deviate from its long history, discussed below, of protecting moral convictions in particular health care contexts. The Departments' implementation of section 2713(a)(4) of the PHS Act with respect to contraceptive coverage is a context similar to those encompassed by many other health care conscience protections provided or supported by Congress. This Mandate concerns contraception and sterilization services, including items believed by some citizens to have an abortifacient effect—that is, to cause the destruction of a human life at an early stage of embryonic development. These are highly sensitive issues in the history of health care regulation and have long been shielded by conscience protections in the laws of the United States.

B. Congress' History of Providing Exemptions for Moral Convictions

In deciding the most appropriate way to exercise our discretion in this context, the Departments draw on nearly 50 years of statutory law and Supreme Court precedent discussing the protection of moral convictions in certain circumstances—particularly in the context of health care and health insurance coverage. Congress very recently expressed its intent on the matter of Government-mandated contraceptive coverage when it declared, with respect to the possibility that the District of Columbia would require contraceptive coverage, that "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808, Public Law 115–31 (May 5, 2017). In support of these interim final rules, we consider it significant that Congress' most recent statement on the prospect of Government mandated contraceptive coverage specifically intends that a conscience clause be included to protect moral convictions.

The many statutes listed in Section I-Background under footnote 1, which show Congress' consistent protection of moral convictions alongside religious beliefs in the Federal regulation of health care, includes laws such as the 1973 Church Amendments, which we discuss at length below, all the way to the 2017 Consolidated Appropriations Act discussed above. Notably among those laws, the Congress has enacted protections for health plans or health care organizations in Medicaid or Medicare Advantage to object "on moral or religious grounds" to providing coverage of certain counseling or referral services. 42 U.S.C. 1395w–

[19] Available at: *https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf* and *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/ACA-FAQs-Part36_1-9-17-Final.pdf.*

22(j)(3)(B) (protecting against forced counseling or referrals in Medicare Choice, now Medicare Advantage, managed care plans with respect to objections based on "moral or religious grounds"); 42 U.S.C. 1396u–2(b)(3) (protecting against forced counseling or referrals in Medicaid managed care plans with respect to objections based on "moral or religious grounds"). The Congress has also protected individuals who object to prescribing or providing contraceptives contrary to their "religious beliefs or moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act), Public Law 115–31.

C. The Church Amendments' Protection of Moral Convictions

One of the most important and well-established federal statutes respecting conscientious objections in specific health care contexts was enacted over the course of several years beginning in 1973, initially as a response to court decisions raising the prospect that entities or individuals might be required to facilitate abortions or sterilizations. These sections of the United States Code are known as the Church Amendments, named after their primary sponsor Senator Frank Church (D–Idaho). The Church Amendments specifically provide conscience protections based on sincerely held moral convictions. Among other things, the amendments protect the recipients of certain Federal health funds from being required to perform, assist, or make their facilities available for abortions or sterilizations if they object "on the basis of religious beliefs or moral convictions," and they prohibit recipients of certain Federal health funds from discriminating against any personnel "because he refused to perform or assist in the performance of such a procedure or abortion on the grounds that his performance or assistance in the performance of the procedure or abortion would be contrary to his religious beliefs or moral convictions" (42 U.S.C. 300a–7(b), (c)(1)). Later additions to the Church Amendments protect other conscientious objections, including some objections on the basis of moral conviction to "any lawful health service," or to "any part of a health service program." (42 U.S.C. 300a–7(c)(2), (d)). In contexts covered by those sections of the Church Amendments, the provision or coverage of certain contraceptives, depending on the circumstances, could constitute "any lawful health service" or a "part of a health service program." As such, the protections provided by those provisions of the Church Amendments would encompass moral objections to contraceptive services or coverage.

The Church Amendments were enacted in the wake of the Supreme Court's decision in *Roe* v. *Wade*, 410 U.S. 113 (1973). Even though the Court in *Roe* required abortion to be legal in certain circumstances, *Roe* did not include, within that right, the requirement that other citizens must facilitate its exercise. Thus, *Roe* favorably quoted the proceedings of the American Medical Association House of Delegates 220 (June 1970), which declared "Neither physician, hospital, nor hospital personnel shall be required to perform any act violative of personally-held moral principles." 410 U.S. at 144 & n.38 (1973). Likewise in *Roe*'s companion case, *Doe* v. *Bolton*, the Court observed that, under State law, "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure." 410 U.S. 179, 197–98 (1973). The Court said that these conscience provisions "obviously . . . afford appropriate protection." *Id.* at 198. As an Arizona court later put it, "a woman's right to an abortion or to contraception does not compel a private person or entity to facilitate either." *Planned Parenthood Ariz., Inc.* v. *Am. Ass'n of Pro-Life Obstetricians & Gynecologists*, 257 P.3d 181, 196 (Ariz. Ct. App. 2011).

The Congressional Record contains relevant discussions that occurred when the protection for moral convictions was first proposed in the Church Amendments. When Senator Church introduced the first of those amendments in 1973, he cited not only *Roe* v. *Wade* but also an instance where a Federal court had ordered a Catholic hospital to perform sterilizations. 119 Congr. Rec. S5717–18 (Mar. 27, 1973). After his opening remarks, Senator Adlai Stevenson III (D–IL) rose to ask that the amendment be changed to specify that it also protects objections to abortion and sterilization based on moral convictions on the same terms as it protects objections based on religious beliefs. The following excerpt of the Congressional Record is particularly relevant to this discussion:

> Mr. STEVENSON. Mr. President, first of all I commend the Senator from Idaho for bringing this matter to the attention of the Senate. I ask the Senator a question.
>
> One need not be of the Catholic faith or any other religious faith to feel deeply about the worth of human life. The protections afforded by this amendment run only to those whose religious beliefs would be offended by the necessity of performing or participating in the performance of certain medical procedures; others, for moral reasons, not necessarily for any religious belief, can feel equally as strong about human life. They too can revere human life.
>
> As mortals, we cannot with confidence say, when life begins. But whether it is life, or the potentiality of life, our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government. Would, therefore, the Senator include moral convictions?
>
> Would the Senator consider an amendment on page 2, line 18 which would add to religious beliefs, the words "or moral"?
>
> Mr. CHURCH. I would suggest to the Senator that perhaps his objective could be more clearly stated if the words "or moral conviction" were added after "religious belief." I think that the Supreme Court in considering the protection we give religious beliefs has given comparable treatment to deeply held moral convictions. I would not be averse to amending the language of the amendment in such a manner. It is consistent with the general purpose. I see no reason why a deeply held moral conviction ought not be given the same treatment as a religious belief.
>
> Mr. STEVENSON. The Senator's suggestion is well taken. I thank him.

119 Congr. Rec. S5717–18.

As the debate proceeded, Senator Church went on to quote *Doe* v. *Bolton*'s reliance on a Georgia statute that stated "a physician or any other employee has the right to refrain, for moral or religious reasons, from participating in the abortion procedure." 119 Congr. Rec. at S5722 (quoting 410 U.S. at 197–98). Senator Church added, "I see no reason why the amendment ought not also to cover doctors and nurses who have strong moral convictions against these particular operations." *Id.* Considering the scope of the protections, Senator Gaylord Nelson (D–WI) asked whether, "if a hospital board, or whatever the ruling agency for the hospital was, a governing agency or otherwise, just capriciously—and not upon the religious or moral questions at all—simply said, 'We are not going to bother with this kind of procedure in this hospital,' would the pending amendment permit that?" 119 Congr. Rec. at S5723. Senator Church responded that the amendment would not encompass such an objection. *Id.*

Senator James L. Buckley (C–NY), speaking in support of the amendment, added the following perspective:

> Mr. BUCKLEY. Mr. President, I compliment the Senator from Idaho for proposing this most important and timely amendment. It is timely in the first instance because the attempt has already been made to compel the performance of abortion and sterilization operations on the part of those who are fundamentally opposed to such procedures. And it is timely also because the

recent Supreme Court decisions will likely unleash a series of court actions across the United States to try to impose the personal preferences of the majority of the Supreme Court on the totality of the Nation.

I believe it is ironic that we should have this debate at all. Who would have predicted a year or two ago that we would have to guard against even the possibility that someone might be free [sic] [20] to participate in an abortion or sterilization against his will? Such an idea is repugnant to our political tradition. This is a Nation which has always been concerned with the right of conscience. It is the right of conscience which is protected in our draft laws. It is the right of conscience which the Supreme Court has quite properly expanded not only to embrace those young men who, because of the tenets of a particular faith, believe they cannot kill another man, but also those who because of their own deepest moral convictions are so persuaded.

I am delighted that the Senator from Idaho has amended his language to include the words "moral conviction," because, of course, we know that this is not a matter of concern to any one religious body to the exclusion of all others, or even to men who believe in a God to the exclusion of all others. It has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred.

119 Congr. Rec. at S5723.

In support of the same protections when they were debated in the U.S. House, Representative Margaret Heckler (R–MA) [21] likewise observed that "the right of conscience has long been recognized in the parallel situation in which the individual's right to conscientious objector status in our selective service system has been protected" and "expanded by the Supreme Court to include moral conviction as well as formal religious belief." 119 Congr. Rec. H4148–49 (May 31, 1973). Rep. Heckler added, "We are concerned here only with the right of moral conscience, which has always been a part of our national tradition." *Id.* at 4149.

These first of the Church Amendments, codified at 42 U.S.C. 300a–7(b) and (c)(1), passed the House 372–1, and were approved by the Senate 94–0. 119 Congr. Rec. at H4149; 119 Congr. Rec. S10405 (June 5, 1973). The subsequently adopted provisions that comprise the Church Amendments similarly extend protection to those organizations and individuals who object to the provision of certain services on the basis of their moral convictions. And, as noted above, subsequent statutes add protections for moral objections in many other situations. These include, for example:

- Protections for individuals and entities that object to abortion: See 42 U.S.C. 238n; 42 U.S.C. 18023; 42 U.S.C. 2996f(b); and Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31;
- Protections for entities and individuals that object to providing or covering contraceptives: See id. at Div. C, Title VIII, Sec. 808; id. at Div. C, Title VII, Sec. 726(c) (Financial Services and General Government Appropriations Act); and id. at Div. I, Title III; and
- Protections for entities and individuals that object to performing, assisting, counseling, or referring as pertains to suicide, assisted suicide, or advance directives: See 42 U.S.C. 290bb–36; 42 U.S.C. 14406; 42 U.S.C. 18113; and 42 U.S.C. 1396a(w)(3).

The Departments believe that the intent behind Congress' protection of moral convictions in certain health care contexts, especially to protect entities and individuals from governmental coercion, supports our decision in these interim final rules to protect sincerely held moral convictions from governmental compulsion threatened by the contraceptive Mandate.

D. Court Precedents Relevant to These Expanded Exemptions

The legislative history of the protection of moral convictions in the first Church Amendments shows that Members of Congress saw the protection as being consistent with Supreme Court decisions. Not only did Senator Church cite the abortion case *Doe* v. *Bolton* as a parallel instance of conscience protection, but he also spoke of the Supreme Court generally giving "comparable treatment to deeply held moral convictions." Both Senator Buckley and Rep. Heckler specifically cited the Supreme Court's protection of moral convictions in laws governing military service. Those legislators appear to have been referencing cases such as *Welsh* v. *United States,* 398 U.S. 333 (1970), which the Supreme Court decided just 3 years earlier.

Welsh involved what is perhaps the Government's paradigmatic compelling interest—the need to defend the nation by military force. The Court stated that, where the Government protects objections to military service based on "religious training and belief," that protection would also extend to avowedly non-religious objections to war held with the same moral strength. *Id.* at 343. The Court declared, "[i]f an individual deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any time, those beliefs certainly occupy in the life of that individual 'a place parallel to that filled by . . . God' in traditionally religious persons. Because his beliefs function as a religion in his life, such an individual is as much entitled to a 'religious' conscientious objector exemption . . . as is someone who derives his conscientious opposition to war from traditional religious convictions."

The Departments look to the description of moral convictions in *Welsh* to help explain the scope of the protection provided in these interim final rules. Neither these interim final rules, nor the Church Amendments or other Federal health care conscience statutes, define "moral convictions" (nor do they define "religious beliefs"). But in issuing these interim final rules, we seek to use the same background understanding of that term that is reflected in the Congressional Record in 1973, in which legislators referenced cases such as *Welsh* to support the addition of language protecting moral convictions. In protecting moral convictions parallel to religious beliefs, *Welsh* describes moral convictions warranting such protection as ones: (1) That the "individual deeply and sincerely holds"; (2) "that are purely ethical or moral in source and content; (3) "but that nevertheless impose upon him a duty"; (4) and that "certainly occupy in the life of that individual a place parallel to that filled by . . . God' in traditionally religious persons," such that one could say "his beliefs function as a religion in his life." (398 U.S. at 339–40). As recited above, Senators Church and Nelson agreed that protections for such moral convictions would not encompass an objection that an individual or entity raises "capriciously." Instead, along with the requirement that protected moral convictions must be "sincerely held," this understanding cabins the protection of moral convictions in contexts where they occupy a place parallel to that filled by sincerely held religious beliefs in religious persons and organizations.

In the context of this particular Mandate, it is also worth noting that, in *Hobby Lobby*, Justice Ginsburg (joined, in this part of the opinion, by Justices Breyer, Kagan, and Sotomayor), cited Justice Harlan's opinion in *Welsh,* 398 U.S. at 357–58, in support of her statement that "[s]eparating moral convictions from religious beliefs would be of questionable legitimacy." 134 S. Ct. at 2789 n.6. In quoting this passage, the Departments do not mean to suggest that all laws protecting only religious

[20] The Senator might have meant "[forced] . . . against his will."

[21] Rep. Heckler later served as the 15th Secretary of HHS, from March 1983 to December 1985.

beliefs constitute an illegitimate "separat[ion]" of moral convictions, nor do we assert that moral convictions must always be protected alongside religious beliefs; we also do not agree with Justice Harlan that distinguishing between religious and moral objections would violate the Establishment Clause. Instead, the Departments believe that, in the specific health care context implicated here, providing respect for moral convictions parallel to the respect afforded to religious beliefs is appropriate, draws from long-standing Federal Government practice, and shares common ground with Congress' intent in the Church Amendments and in later Federal conscience statutes that provide protections for moral convictions alongside religious beliefs in other health care contexts.

E. Conscience Protections in Regulations and Among the States

The tradition of protecting moral convictions in certain health contexts is not limited to Congress. Multiple federal regulations protect objections based on moral convictions in such contexts.[22] Other federal regulations have also applied the principle of respecting moral convictions alongside religious beliefs when they have determined that it is appropriate to do so in particular circumstances. The Equal Employment Opportunity Commission has consistently protected "moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views" alongside religious views under the "standard [] developed in *United States* v. *Seeger*, 380 U.S. 163 (1965) and [*Welsh*]." (29 CFR 1605.1). The Department of Justice has declared that, in cases of capital punishment, no officer or employee may be required to attend or participate if doing so "is contrary to the moral or religious convictions of the officer or employee, or if the employee is a medical professional who considers such participation or attendance contrary to medical ethics." (28 CFR 26.5).[23]

Forty-five States have health care conscience protections covering objections to abortion, and several of those also cover sterilization or contraception.[24] Most of those State laws protect objections based on "moral," "ethical," or "conscientious" grounds in addition to "religious" grounds. Particularly in the case of abortion, some Federal and State conscience laws do not require any specified motive for the objection. (42 U.S.C. 238n). These various statutes and regulations reflect an important governmental interest in protecting moral convictions in appropriate health contexts.

The contraceptive Mandate implicates that governmental interest. Many persons and entities object to this Mandate in part because they consider some forms of FDA-approved contraceptives to be abortifacients and morally equivalent to abortion due to the possibility that some of the items may have the effect of preventing the implantation of a human embryo after fertilization. Based on our knowledge from the litigation, all of the current litigants asserting purely non-religious objections share this view, and most of the religious litigants do as well. The Supreme Court, in describing family business owners with religious objections, explained that "[t]he owners of the businesses have religious objections to abortion, and according to their religious beliefs the four contraceptive methods at issue are abortifacients. If the owners comply with the HHS mandate, they believe they will be facilitating abortions." *Hobby Lobby*, 134 S. Ct. at 2751. Outside of the context of abortion, as cited above, Congress has also provided health care conscience protections pertaining to sterilization, contraception, and other health care services and practices.

F. Founding Principles

The Departments also look to guidance from the broader history of respect for conscience in the laws and founding principles of the United States. Members of Congress specifically relied on the American tradition of respect for conscience when they decided to protect moral convictions in health care. As quoted above, in supporting protecting conscience based on non-religious moral convictions, Senator Buckley declared "[i]t has been a traditional concept in our society from the earliest times that the right of conscience, like the paramount right to life from which it is derived, is sacred." Rep. Heckler similarly stated that "the right of moral conscience . . . has always been a part of our national tradition." This tradition is reflected, for example, in a letter President George Washington wrote saying that "[t]he Citizens of the United States of America have a right to applaud themselves for having given to mankind examples of an enlarged and liberal policy: A policy worthy of imitation. All possess alike liberty of conscience and immunities of citizenship."[25] Thomas Jefferson similarly declared that "[n]o provision in our Constitution ought to be dearer to man than that which protects the rights of conscience against the enterprises of the civil authority."[26] Although these statements by Presidents Washington and Jefferson were spoken to religious congregations, and although religious and moral conscience were tightly intertwined for the Founders, they both reflect a broad principle of respect for conscience against government coercion. James Madison likewise called conscience "the most sacred of all property," and proposed that the Bill of Rights should guarantee, in addition to protecting religious belief and worship, that "the full and equal rights of conscience [shall not] be in any manner, or on any pretext infringed."[27]

These Founding Era statements of general principle do not specify how they would be applied in a particular health care context. We do not suggest that the specific protections offered in this rule would also be required or necessarily appropriate in any other context that does not raise the specific concerns implicated by this Mandate. These interim final rules do not address in any way how the Government would balance its interests with respect to

[22] *See, for example*, 42 CFR 422.206 (declaring that the general Medicare Advantage rule "does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—(1) Objects to the provision of that service on moral or religious grounds."); 42 CFR 438.102 (declaring that information requirements do not apply "if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds"); 48 CFR 1609.7001 ("health plan sponsoring organizations are not required to discuss treatment options that they would not ordinarily discuss in their customary course of practice because such options are inconsistent with their professional judgment or ethical, moral or religious beliefs."); 48 CFR 352.270–9 ("Non-Discrimination for Conscience" clause for organizations receiving HIV or Malaria relief funds).

[23] *See also* 18 CFR 214.11 (where a law enforcement agency (LEA) seeks assistance in the investigation or prosecution of trafficking of persons, the reasonableness of the LEA's request will depend in part on "[c]ultural, religious, or moral objections to the request").

[24] According to the Guttmacher Institute, 45 states have conscience statutes pertaining to abortion (43 of which cover institutions), 18 have conscience statutes pertaining to sterilization (16 of which cover institutions), and 12 have conscience statutes pertaining to contraception (8 of which cover institutions). "Refusing to Provide Health Services" (June 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services*.

[25] From George Washington to the Hebrew Congregation in Newport, Rhode Island (Aug. 18, 1790), available at *https://founders.archives.gov/documents/Washington/05-06-02-0135*.

[26] Letter to the Society of the Methodist Episcopal Church at New London, Connecticut (February 4, 1809), available at *https://founders.archives.gov/documents/Jefferson/99-01-02-9714*.

[27] James Madison, "Essay on Property" (March 29, 1792); First draft of the First Amendment, 1 Annals of Congress 434 (June 8, 1789).

other health services not encompassed by the contraceptive Mandate.[28] Instead we highlight this tradition of respect for conscience from our Founding Era to provide background support for the Departments' decision to implement section 2713(a)(4) of the PHS Act, while protecting conscience in the exercise of moral convictions. We believe that these interim final rules are consistent both with the American tradition of respect for conscience and with Congress' history of providing conscience protections in the kinds of health care matters involved in this Mandate.

G. Executive Orders Relevant to These Expanded Exemptions

Protecting moral convictions, as set forth in the expanded exemptions and accommodations of these rules, is consistent with recent executive orders. President Trump's Executive Order concerning this Mandate directed the Departments to consider providing protections, not specifically for "religious" beliefs, but for "conscience." We interpret that term to include moral convictions and not just religious beliefs. Likewise, President Trump's first Executive Order, EO 13765, declared that "the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." This Mandate imposes both a cost, fee, tax, or penalty, and a regulatory burden, on individuals and purchasers of health insurance that have moral convictions opposed to providing contraceptive coverage. These interim final rules exercise the Departments' discretion to grant exemptions from the Mandate to reduce and relieve regulatory burdens and promote freedom in the health care market.

[28] As the Supreme Court stated in *Hobby Lobby*, the Court's decision concerns only the contraceptive Mandate, and should not be understood to hold that all insurance-coverage mandates, for example, for vaccinations or blood transfusions, must necessarily fail if they conflict with an employer's religious beliefs. Nor does the Court's opinion provide a shield for employers who might cloak illegal discrimination as a religious (or moral) practice. 134 S. Ct. at 2783.

H. Litigation Concerning the Mandate

The sensitivity of certain health care matters makes it particularly important for the Government to tread carefully when engaging in regulation concerning those areas, and to respect individuals and organizations whose moral convictions are burdened by Government regulations. Providing conscience protections advances the Affordable Care Act's goal of expanding health coverage among entities and individuals that might otherwise be reluctant to participate in the market. For example, the Supreme Court in *Hobby Lobby* declared that, if HHS requires owners of businesses to cover procedures that the owners "could not in good conscience" cover, such as abortion, "HHS would effectively exclude these people from full participation in the economic life of the Nation." 134 S. Ct. at 2783. That would be a serious outcome. As demonstrated by litigation and public comments, various citizens sincerely hold moral convictions, which are not necessarily religious, against providing or participating in coverage of contraceptive items included in the Mandate, and some believe that some of those items may cause early abortions. The Departments wish to implement the contraceptive coverage Guidelines issued under section 2713(a)(4) of the PHS Act in a way that respects the moral convictions of our citizens so that they are more free to engage in "full participation in the economic life of the Nation." These expanded exemptions do so by removing an obstacle that might otherwise lead entities or individuals with moral objections to contraceptive coverage to choose not to sponsor or participate in health plans if they include such coverage.

Among the lawsuits challenging the Mandate, two have been filed based in part on non-religious moral convictions. In one case, the Departments are subject to a permanent injunction requiring us to respect the non-religious moral objections of an employer. *See March for Life* v. *Burwell*, 128 F. Supp. 3d 116 (D.D.C. 2015). In the other case, an appeals court recently affirmed a district court ruling that allows the previous regulations to be imposed in a way that violates the moral convictions of a small nonprofit pro-life organization and its employees. *See Real Alternatives*, 2017 WL 3324690. Our litigation of these cases has led to inconsistent court rulings, consumed substantial governmental resources, and created uncertainty for objecting organizations, issuers, third party administrators, and employees and beneficiaries. The organizations that have sued seeking a moral exemption have all adopted moral tenets opposed to contraception and hire only employees who share this view. It is reasonable to conclude that employees of these organizations would therefore not benefit from the Mandate. As a result, subjecting this subset of organizations to the Mandate does not advance any governmental interest. The need to resolve this litigation and the potential concerns of similar entities, and our requirement to comply with permanent injunctive relief currently imposed in *March for Life*, provide substantial reasons for the Departments to protect moral convictions through these interim final rules. Even though, as discussed below, we assume the number of entities and individuals that may seek exemption from the Mandate on the basis of moral convictions, as these two sets of litigants did, will be small, we know from the litigation that it will not be zero. As a result, the Departments have taken these types of objections into consideration in reviewing our regulations. Having done so, we consider it appropriate to issue the protections set forth in these interim final rules. Just as Congress, in adopting the early provisions of the Church Amendments, viewed it as necessary and appropriate to protect those organizations and individuals with objections to certain health care services on the basis of moral convictions, so we, too, believe that "our moral convictions as well as our religious beliefs, warrant protection from this intrusion by the Government" in this situation.

I. The Departments' Rebalancing of Government Interests

For additional discussion of the Government's balance of interests concerning religious beliefs issued contemporaneously with these interim final rules, see the related document published by the Department elsewhere in this issue of the **Federal Register**. There, we acknowledge that the Departments have changed the policies and interpretations we previously adopted with respect to the Mandate and the governmental interests that underlying it, and we assert that we now believe the Government's legitimate interests in providing for contraceptive coverage do not require us to violate sincerely held religious beliefs while implementing the Guidelines. For parallel reasons, the Departments believe Congress did not set forth—and we do not possess—interests that require us to violate sincerely held moral convictions in the course of generally requiring contraceptive coverage. These changes in policy are

within the Departments' authority. As the Supreme Court has acknowledged, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC* v. *Navarro*, 136 S. Ct. 2117, 2125 (2016). This "reasoned analysis" requirement does not demand that an agency "demonstrate to a court's satisfaction that the reasons for the new policy are better than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes it to be better, which the conscious change of course adequately indicates." *United Student Aid Funds, Inc.* v. *King*, 200 F. Supp. 3d 163, 169–70 (D.D.C. 2016) (citing *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)); *see also New Edge Network, Inc.* v. *FCC*, 461 F.3d 1105, 1112–13 (9th Cir. 2006) (rejecting an argument that "an agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change beyond that which may be required when an agency does not act in the first instance").[29]

The Departments note that the exemptions created here, like the exemptions created by the last Administration, do not burden third parties to a degree that counsels against providing the exemptions. In addition to the apparent fact that many entities with non-religious moral objections to the Mandate appear to only hire persons that share those objections, Congress did not create a right to receive contraceptive coverage, and Congress explicitly chose not to impose the section 2713 requirements on grandfathered plans benefitting millions of people. Individuals who are unable to obtain contraceptive coverage through their employer-sponsored health plans because of the exemptions created in these interim final rules, or because of other exemptions to the Mandate, have other avenues for obtaining contraception, including through various other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women, and which these interim final rules leave unchanged.[30] As the Government is under no constitutional obligation to fund contraception, *cf. Harris* v. *McRae*, 448 U.S. 297 (1980), even more so may the Government refrain from requiring private citizens to cover contraception for other citizens in violation of their moral convictions. *Cf. Rust* v. *Sullivan*, 500 U.S. 173, 192–93 (1991) ("A refusal to fund protected activity, without more, cannot be equated with the imposition of a 'penalty' on that activity.").

The Departments acknowledge that coverage of contraception is an important and highly controversial issue, implicating many different views, as reflected for example in the public comments received on multiple rulemakings over the course of implementation of section 2713(a)(4) of the PHS Act. Our expansion of conscience protections for moral convictions, similar to protections contained in numerous statutes governing health care regulation, is not taken lightly. However, after reconsidering the interests served by the Mandate in this particular context, the objections raised, and the relevant Federal law, the Departments have determined that expanding the exemptions to include protections for moral convictions is a more appropriate administrative response than continuing to refuse to extend the exemptions and accommodations to certain entities and individuals for whom the Mandate violates their sincerely held moral convictions. Although the number of organizations and individuals that may seek to take advantage of these exemptions and accommodations may be small, we believe that it is important formally to codify such protections for objections based on moral conviction, given the long-standing recognition of such protections in health care and health insurance context in law and regulation and the particularly sensitive nature of these issues in the health care context. These interim final rules leave unchanged HRSA's authority to decide whether to include contraceptives in the women's preventive services Guidelines for entities that are not exempted by law, regulation, or the Guidelines. These rules also do not change the many other mechanisms by which the Government advances contraceptive coverage, particularly for low-income women.

III. Provisions of the Interim Final Rules With Comment Period

The Departments are issuing these interim final rules in light of the full history of relevant rulemaking (including 3 previous interim final rules), public comments, and the long-running litigation from non-religious moral objectors to the Mandate, as well as the information contained in the companion interim final rules issued elsewhere in this issue of the **Federal Register**. These interim final rules seek to resolve these matters by directing HRSA, to the extent it requires coverage for certain contraceptive services in its Guidelines, to afford an exemption to certain entities and individuals with sincerely held moral convictions by which they object to contraceptive or sterilization coverage, and by making the accommodation process available for certain organizations with such convictions.

For all of the reasons discussed and referenced above, the Departments have determined that the Government's interest in applying contraceptive coverage requirements to the plans of certain entities and individuals does not outweigh the sincerely held moral objections of those entities and individuals. Thus, these interim final rules amend the regulations amended in both the Departments' July 2015 final regulations and in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

These interim final rules expand those exemptions to include additional entities and persons that object based on sincerely held moral convictions. These rules leave in place HRSA's discretion to continue to require contraceptive and sterilization coverage where no objection specified in the regulations exists, and if section 2713 of the PHS Act otherwise applies. These interim final rules also maintain the existence of an accommodation process as a voluntary option for organizations with moral objections to contraceptive coverage, but consistent with our expansion of the exemption, we expand eligibility for the accommodation to include organizations with sincerely held moral convictions concerning contraceptive coverage. HRSA is simultaneously updating its Guidelines to reflect the requirements of these interim final rules.[31]

[29] *See also Chevron, U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 863–64 (1984) ("The fact that the agency has adopted different definitions in different contexts adds force to the argument that the definition itself is flexible, particularly since Congress has never indicated any disapproval of a flexible reading of the statute.")

[30] *See, for example,* Family Planning grants in 42 U.S.C. 300, *et seq.;* the Teenage Pregnancy Prevention Program, Public Law 112–74 (125 Stat 786, 1080); the Healthy Start Program, 42 U.S.C. 254c–8; the Maternal, Infant, and Early Childhood Home Visiting Program, 42 U.S.C. 711; Maternal and Child Health Block Grants, 42 U.S.C. 703; 42 U.S.C. 247b–12; Title XIX of the Social Security Act, 42 U.S.C. 1396, *et seq.;* the Indian Health Service, 25 U.S.C. 13, 42 U.S.C. 2001(a), & 25 U.S.C. 1601, *et seq.;* Health center grants, 42 U.S.C. 254b(e), (g), (h), & (i); the NIH Clinical Center, 42 U.S.C. 248; and the Personal Responsibility Education Program, 42 U.S.C. 713.

[31] *See https://www.hrsa.gov/womensguidelines/* and *https://www.hrsa.gov/womensguidelines2016/index.html.*

1. Exemption for Objecting Entities Based on Moral Convictions

In the new 45 CFR 147.133 as created by these interim final rules, we expand the exemption that was previously located in § 147.131(a), and that was expanded in § 147.132 by the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

With respect to employers that sponsor group health plans, § 147.133(a)(1) and (a)(1)(i) provide exemptions for certain employers that object to coverage of all or a subset of contraceptives or sterilization and related patient education and counseling based on sincerely held moral convictions.

For avoidance of doubt, the Departments wish to make clear that the expanded exemption in § 147.133(a) applies to several distinct entities involved in the provision of coverage to the objecting employer's employees. This explanation is consistent with how prior rules have worked by means of similar language. Section 147.133(a)(1) and (a)(1)(i), by specifying that "[a] group health plan and health insurance coverage provided in connection with a group health plan" is exempt "to the extent the plan sponsor objects as specified in paragraph (a)(2)," exempt the group health plans the sponsors of which object, and exempt their health insurance issuers in providing the coverage in those plans (whether or not the issuers have their own objections). Consequently, with respect to Guidelines issued under § 147.130(a)(1)(iv), or the parallel provisions in 26 CFR 54.9815–2713T(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), the plan sponsor, issuer, and plan covered in the exemption of that paragraph would face no penalty as a result of omitting contraceptive coverage from the benefits of the plan participants and beneficiaries.

Consistent with the restated exemption, exempt entities will not be required to comply with a self-certification process. Although exempt entities do not need to file notices or certifications of their exemption, and these interim final rules do not impose any new notice requirements on them, existing ERISA rules governing group health plans require that, with respect to plans subject to ERISA, a plan document must include a comprehensive summary of the benefits covered by the plan and a statement of the conditions for eligibility to receive benefits. Under ERISA, the plan document provides what benefits are provided to participants and beneficiaries under the plan and, therefore, if an objecting employer would like to exclude all or a subset of contraceptive services, it must ensure that the exclusion is clear in the plan document. Moreover, if there is a reduction in a covered service or benefit, the plan has to disclose that change to plan participants.[32] Thus, where an exemption applies and all or a subset of contraceptive services are omitted from a plan's coverage, otherwise applicable ERISA disclosures should reflect the omission of coverage in ERISA plans. These existing disclosure requirements serve to help provide notice to participants and beneficiaries of what ERISA plans do and do not cover. The Departments invite public comment on whether exempt entities, or others, would find value either in being able to maintain or submit a specific form of certification to claim their exemption, or in otherwise receiving guidance on a way to document their exemption.

The exemptions in § 147.133(a) apply "to the extent" of the objecting entities' sincerely held moral convictions. Thus, entities that hold a requisite objection to covering some, but not all, contraceptive items would be exempt with respect to the items to which they object, but not with respect to the items to which they do not object. Likewise, the requisite objection of a plan sponsor or institution of higher education in § 147.133(a)(1)(i) and (ii) exempts its group health plan, health insurance coverage offered by a health insurance issuer in connection with such plan, and its issuer in its offering of such coverage, but that exemption does not extend to coverage provided by that issuer to other group health plans where the plan sponsors have no qualifying objection. The objection of a health insurance issuer in § 147.133(a)(1)(iii) similarly operates only to the extent of its objection, and as otherwise limited as described below.

2. Exemption of Certain Plan Sponsors

The rules cover certain kinds of non-governmental employer plan sponsors with the requisite objections, and the rules specify which kinds of entities qualify for the exemption.

Under these interim final rules, the Departments do not limit the exemption with reference to nonprofit status as previous rules have done. Many of the federal health care conscience statutes cited above offer protections for the moral convictions of entities without regard to whether they operate as nonprofits or for-profit entities. In addition, a significant majority of states either impose no contraceptive coverage requirement, or offer broader exemptions than the exemption contained in the July 2015 final regulations.[33] States also generally protect moral convictions in health care conscience laws, and they often offer those protections whether or not an entity operates as a nonprofit.[34] Although the practice of states is by no means a limit on the discretion delegated to HRSA by the Affordable Care Act, nor is it a statement about what the Federal Government may do consistent with other protections or limitations in federal law, such state practice can be informative as to the viability of offering protections for conscientious objections in particularly sensitive health care contexts. In this case, the existence of many instances where conscience protections are offered, or no underlying mandate of this kind exists that could violate moral convictions, supports the Departments' decision to expand the Federal exemption concerning this Mandate as set forth in these interim final rules.

Section 147.133(a)(1)(i)(A) of the rules specifies that the exemption includes the plans of a plan sponsor that is a nonprofit organization with sincerely held moral convictions.

Section 147.133(a)(1)(i)(B) of the rules specifies that the exemption includes the plans of a plan sponsor that is a for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

Extending the exemption to certain for-profit entities is consistent with the Supreme Court's ruling in *Hobby Lobby*, which declared that a corporate entity is capable of possessing and pursuing non-pecuniary goals (in *Hobby Lobby*, religion), regardless of whether the entity operates as a nonprofit organization, and rejecting the

[32] *See, for example*, 29 U.S.C. 1022, 1024(b), 29 CFR 2520.102–2, 2520.102–3, & 2520.104b–3(d), and 29 CFR 2590.715–2715. *See also* 45 CFR 147.200 (requiring disclosure of the "exceptions, reductions, and limitations of the coverage," including group health plans and group & individual issuers).

[33] *See* Guttmacher Institute, "Insurance Coverage of Contraceptives" (Aug. 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives*.

[34] *See, for example*, Guttmacher Institute, "Refusing to Provide Health Services" (Aug. 1, 2017), available at *https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services*.

Departments' argument to the contrary. 134 S. Ct. 2768–75. Some reports and industry experts have indicated that not many for-profit entities beyond those that had originally brought suit have sought relief from the Mandate after *Hobby Lobby*.[35] The mechanisms for determining whether a company has adopted and holds certain principles or views, such as sincerely held moral convictions, is a matter of well-established State law with respect to corporate decision-making,[36] and the Departments expect that application of such laws would cabin the scope of this exemption.

The July 2015 final regulations extended the accommodation to for-profit entities only if they are closely held, by positively defining what constitutes a closely held entity. Any such positive definition runs up against the myriad state differences in defining such entities, and potentially intrudes into a traditional area of state regulation of business organizations. The Departments implicitly recognized the difficulty of defining closely held entities in the July 2015 final regulations when we adopted a definition that included entities that are merely "substantially similar" to certain specified parameters, and we allowed entities that were not sure if they met the definition to inquire with HHS; HHS was permitted to decline to answer the inquiry, at which time the entity would be deemed to qualify as an eligible organization. Instead of attempting to positively define closely held businesses for the purpose of this rule, the Departments consider it much more clear, effective, and preferable to define the category negatively by reference to one element of our previous definition, namely, that the entity has no publicly traded ownership interest (that is, any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934).

In this way, these interim final rules differ from the exemption provided to plan sponsors with objections based on sincerely held religious beliefs set forth in § 147.132(a)(1)—those extend to for-profit entities whether or not they are closely held or publicly traded. The Departments seek public comment on whether the exemption in § 147.133(a)(1)(i) for plan sponsors with moral objections to the Mandate should be finalized to encompass all of the types of plan sponsors covered by § 147.132(a)(1)(i), including publicly traded corporations with objections based on sincerely held moral convictions, and also non-federal governmental plan sponsors that may have objections based on sincerely held moral convictions.

In the case of particularly sensitive health care matters, several significant federal health care conscience statutes protect entities' moral objections without precluding publicly traded and governmental entities from using those protections. For example, the first paragraph of the Church Amendments provides certain protections for entities that object based on moral convictions to making their facilities or personnel available to assist in the performance of abortions or sterilizations, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 300a–7(b)). Thus, under section 300a–7(b), a hospital in a publicly traded health system, or a local governmental hospital, could adopt sincerely held moral convictions by which it objects to providing facilities or personnel for abortions or sterilizations, and if the entity receives relevant funds from HHS specified by section 300a–7(b), the protections of that section would apply. The Coats-Snowe Amendment likewise provides certain protections for health care entities and postgraduate physician training programs that choose not to perform, refer for, or provide training for abortions, and the statute does not limit those protections based on whether the entities are publicly traded or governmental. (42 U.S.C. 238n).

The Weldon Amendment[37] provides certain protections for health care entities, hospitals, provider-sponsored organizations, health maintenance organizations, and health insurance plans that do not provide, pay for, provide coverage of, or refer for abortions, and the statute does not limit those protections based on whether the entity is publicly traded or governmental. The Affordable Care Act provides certain protections for any institutional health care entity, hospital, provider-sponsored organization, health maintenance organization, health insurance plan, or any other kind of health care facility, that does not provide any health care item or service furnished for the purpose of causing or assisting in causing assisted suicide, euthanasia, or mercy killing, and the statute similarly does not limit those protections based on whether the entity is publicly traded or governmental. (42 U.S.C. 18113).[38]

Sections 1395w–22(j)(3)(B) and 1396u–2(b)(3) of 42 U.S.C. protect organizations that offer Medicaid and Medicare Advantage managed care plans from being required to provide, reimburse for, or provide coverage of a counseling or referral service if they object to doing so on moral grounds, and those paragraphs do not further specify that publicly traded entities do not qualify for the protections. Congress' most recent statement on Government requirements of contraceptive coverage specified that, if the District of Columbia requires "the provision of contraceptive coverage by health insurance plans," "it is the intent of Congress that any legislation enacted on such issue should include a 'conscience clause' which provides exceptions for religious beliefs and moral convictions." Consolidated Appropriations Act of 2017, Division C, Title VIII, Sec. 808. Congress expressed no intent that such a conscience should be limited based on whether the entity is publicly traded.

At the same time, the Departments lack significant information about the need to extend the expanded exemption further. We have been subjected to litigation by nonprofit entities expressing objections to the Mandate based on non-religious moral convictions, and we have been sued by closely held for-profit entities expressing religious objections. This combination of different types of plaintiffs leads us to believe that there may be a small number of closely held for-profit entities that would seek to use an exemption to the contraceptive Mandate based on moral convictions. The fact that many closely held for-profit entities brought challenges to the Mandate has led us to offer protections that would include publicly traded entities with religious objections to the Mandate if such entities exist. But the combined lack of any lawsuits challenging the Mandate by for-profit entities with non-religious moral convictions, and of any lawsuits by any kind of publicly traded entity, leads us to not extend the expanded exemption in these interim final rules to publicly traded entities, but rather to invite public comment on whether to do so in

[35] See Jennifer Haberkorn, "Two years later, few Hobby Lobby copycats emerge," *Politico* (Oct. 11, 2016), available at *http://www.politico.com/story/2016/10/obamacare-birth-control-mandate-employers-229627*.

[36] Although the Departments do not prescribe any form or notification, they would expect that such principles or views would have been adopted and documented in accordance with the laws of the jurisdiction under which they are incorporated or organized.

[37] Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Pub. L. 115–31.

[38] The lack of the limitation in this provision may be particularly relevant since it is contained in the same statute, the ACA, as the provision under which the Mandate—and these exemptions to the Mandate—are promulgated.

a way parallel to the protections set forth in § 147.132(a)(1)(i). We agree with the Supreme Court that it is improbable that many publicly traded companies with numerous "unrelated shareholders—including institutional investors with their own set of stakeholders—would agree to run a corporation under the same religious beliefs" (or moral convictions) and thereby qualify for the exemption. *Hobby Lobby*, 134 S. Ct. at 2774. We are also not aware of other types of plan sponsors (such as non-Federal governmental entities) that might possess moral objections to compliance with the Mandate, including whether some might consider certain contraceptive methods as having a possible abortifacient effect. Nevertheless, we would welcome any comments on whether such corporations or other plan sponsors exist and would benefit from such an exemption.

Despite our a lack of complete information, the Departments know that nonprofit entities have challenged the Mandate, and we assume that a closely held business might wish to assert non-religious moral convictions in objecting to the Mandate (although we anticipate very few if any will do so). Thus we have chosen in these interim final rules to include them in the expanded exemption and thereby remove an obstacle preventing such entities from claiming an exemption based on non-religious moral convictions. But we are less certain that we need to use these interim final rules to extend the expanded exemption for moral convictions to encompass other kinds of plan sponsors not included in the protections of these interim final rules. Therefore, with respect to plan sponsors not included in the expanded exemptions of § 147.133(a)(1)(i), and non-federal governmental plan sponsors that might have moral objections to the Mandate, we invite public comment on whether to include such entities when we finalize these rules at a later date.

The Departments further conclude that it would be inadequate to merely provide entities access to the accommodation process instead of to the exemption where those entities object to the Mandate based on sincerely held moral convictions. The Departments have stated in our regulations and court briefings that the existing accommodation with respect to self-insured plans requires contraceptive coverage as part of the same plan as the coverage provided by the employer, and operates in a way "seamless" to those plans. As a result, in significant respects, the accommodation process does not actually accommodate the objections of many entities. This has led many religious groups to challenge the accommodation in court, and we expect similar challenges would come from organizations objecting to the accommodation based on moral convictions if we offered them the accommodation but not an exemption. When we took that narrow approach with religious nonprofit entities it led to multiple cases in many courts that we needed to litigate to the Supreme Court various times. Although objections to the accommodation were not specifically litigated in the two cases brought by nonprofit non-religious organizations (because we have not even made them eligible for the accommodation), those organizations made it clear that they and their employees strongly oppose coverage of certain contraceptives in their plans and in connection with their plans.

3. Exemption for Institutions of Higher Education

The plans of institutions of higher education that arrange student health insurance coverage will be treated similarly to the way that plans of employers are treated for the purposes of such plans being exempt or accommodated based on moral convictions. These interim final rules specify, in § 147.133(a)(1)(ii), that the exemption is extended, in the case of institutions of higher education (as defined in 20 U.S.C. 1002), to their arrangement of student health insurance coverage, in a manner comparable to the applicability of the exemption for group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor.

The Departments are not aware of institutions of higher education that arrange student coverage and object to the Mandate based on non-religious moral convictions. We have been sued by several institutions of higher education that arrange student coverage and object to the Mandate based on religious beliefs. We believe the existence of such entities with non-religious moral objections, or the possible formation of such entities in the future, is sufficiently possible so that we should provide protections for them in these interim final rules. But based on a lack of information about such entities, we assume that none will use the exemption concerning student coverage at this time.

4. Exemption for Issuers

These interim final rules extend the exemption, in § 147.133(a)(1)(iii), to health insurance issuers offering group or individual health insurance coverage that sincerely hold their own moral convictions opposed to providing coverage for contraceptive services.

As discussed above, where the exemption for plan sponsors or institutions of higher education applies, issuers are exempt under those sections with respect to providing coverage in those plans. The issuer exemption in § 147.133(a)(1)(iii) adds to that protection, but the additional protection operates in a different way than the plan sponsor exemption operates. The only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an exempt issuer that does not cover some or all contraceptive services are plan sponsors or individuals who themselves object and are otherwise exempt based on their objection (whether the objection is based on moral convictions, as set forth in these rules, or on religious beliefs, as set forth in exemptions created by the companion interim final rules published elsewhere in this issue of the **Federal Register**). Thus, the issuer exemption specifies that where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless the plan is otherwise exempt from that requirement. Accordingly, the only plan sponsors, or in the case of individual insurance coverage, individuals, who are eligible to purchase or enroll in health insurance coverage offered by an issuer that is exempt under this paragraph (a)(1)(iii) that does not include some or all contraceptive services are plan sponsors or individuals who themselves object and are exempt.

Under the rules as amended, issuers with objections based on sincerely held moral convictions could issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions, and issuers with sincerely held religious beliefs could likewise issue policies that omit contraception to plan sponsors or individuals that are otherwise exempt based on either their religious beliefs or their moral convictions.

Issuers that hold moral objections should identify to plan sponsors the

lack of contraceptive coverage in any health insurance coverage being offered that is based on the issuer's exemption, and communicate the group health plan's independent obligation to provide contraceptive coverage, unless the group health plan itself is exempt under regulations governing the Mandate.

In this way, the issuer exemption serves to protect objecting issuers both from being asked or required to issue policies that cover contraception in violation of the issuers' sincerely held moral convictions, and from being asked or required to issue policies that omit contraceptive coverage to non-exempt entities or individuals, thus subjecting the issuers to potential liability if those plans are not exempt from the Guidelines. At the same time, the issuer exemption will not serve to remove contraceptive coverage obligations from any plan or plan sponsor that is not also exempt, nor will it prevent other issuers from being required to provide contraceptive coverage in individual insurance coverage. Protecting issuers that object to offering contraceptive coverage based on sincerely held moral convictions will help preserve space in the health insurance market for certain issuers so that exempt plan sponsors and individuals will be able to obtain coverage.

The Departments are not currently aware of health insurance issuers that possess their own religious or moral objections to offering contraceptive coverage. Nevertheless, many Federal health care conscience laws and regulations protect issuers or plans specifically. For example, as discussed above, 42 U.S.C. 1395w–22(j)(3)(B) and 1396u–2(b)(3) protect plans or managed care organizations in Medicaid or Medicare Advantage. The Weldon Amendment protects HMOs, health insurance plans, and any other health care organizations from being required to provide coverage or pay for abortions. *See, for example,* Consolidated Appropriations Act of 2017, Div. H, Title V, Sec. 507(d), Public Law 115–31. The most recently enacted Consolidated Appropriations Act declares that Congress supports a "conscience clause" to protect moral convictions concerning "the provision of contraceptive coverage by health insurance plans." *See id.* at Div. C, Title VIII, Sec. 808.

The issuer exemption does not specifically include third party administrators, for the reasons discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. The Departments solicit public comment; however, on whether there are situations where there may be an additional need to provide distinct protections for third party administrators that may have moral convictions implicated by the Mandate.[39]

5. Scope of Objections Needed for the Objecting Entity Exemption

Exemptions for objecting entities specify that they apply where the entities object as specified in § 147.133(a)(2). That section specifies that exemptions for objecting entities will apply to the extent that an entity described in § 147.133(a)(1) objects to its establishing, maintaining, providing, offering, or arranging (as applicable) for coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held moral convictions.

6. Individual Exemption

These interim final rules include a special rule pertaining to individuals (referred to here as the "individual exemption"). Section 147.133(b) provides that nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713T(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv), may be construed to prevent a willing plan sponsor of a group health plan and/or a willing health insurance issuer offering group or individual health insurance coverage, from offering a separate benefit package option, or a separate policy, certificate, or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on the individual's sincerely held moral convictions. The individual exemption extends to the coverage unit in which the plan participant, or subscriber in the individual market, is enrolled (for instance, to family coverage covering the participant and his or her beneficiaries enrolled under the plan), but does not relieve the plan's or issuer's obligation to comply with the Mandate with respect to the group health plan at large or, as applicable, to any other individual policies the issuer offers.

This individual exemption allows plan sponsors and issuers that do not specifically object to contraceptive coverage to offer morally acceptable coverage to their participants or subscribers who do object, while offering coverage that includes contraception to participants or subscribers who do not object. This individual exemption can apply with respect to individuals in plans sponsored by private employers or governmental employers. For example, in one case brought against the Departments, the State of Missouri enacted a law under which the State is not permitted to discriminate against insurance issuers that offer health plans without coverage for contraception based on employees' moral convictions, or against the individual employees who accept such offers. *See Wieland,* 196 F. Supp. 3d at 1015–16 (quoting Mo. Rev. Stat. 191.724). Under the individual exemption of these interim final rules, employers sponsoring governmental plans would be free to honor the sincerely held moral objections of individual employees by offering them plans that omit contraception, even if those governmental entities do not object to offering contraceptive coverage in general.

This "individual exemption" cannot be used to force a plan (or its sponsor) or an issuer to provide coverage omitting contraception, or, with respect to health insurance coverage, to prevent the application of state law that requires coverage of such contraceptives or sterilization. Nor can the individual exemption be construed to require the guaranteed availability of coverage omitting contraception to a plan sponsor or individual who does not have a sincerely held moral objection. This individual exemption is limited to the requirement to provide contraceptive coverage under section 2713(a)(4) of the PHS Act, and does not affect any other federal or state law governing the plan or coverage. Thus, if there are other applicable laws or plan terms governing the benefits, these interim final rules do not affect such other laws or terms.

The Departments believe the individual exemption will help to meet the Affordable Care Act's goal of increasing health coverage because it will reduce the incidence of certain individuals choosing to forego health coverage because the only coverage available would violate their sincerely held moral convictions.[40] At the same

[39] The exemption for issuers, as outlined here, does not make a distinction among issuers based on whether they are publicly traded, unlike the plan sponsor exemption for business entities. Because the issuer exemption operates more narrowly than the exemption for business plan sponsors operates, in the ways described here, and exists in part to help preserve market options for objecting plan sponsors, the Departments consider it appropriate to not draw such a distinction among issuers.

[40] This prospect has been raised in cases of religious individuals—see, for example, *Wieland,*

Continued

time, this individual exemption "does not undermine the governmental interests furthered by the contraceptive coverage requirement,"[41] because, when the exemption is applicable, the individual does not want the coverage, and therefore would not use the objectionable items even if they were covered. In addition, because the individual exemption only operates when the employer and/or issuer, as applicable, are willing, the exemption will not undermine any governmental interest in the workability of the insurance market, because we expect that any workability concerns will be taken into account in the decision of whether to be willing to offer the individual morally acceptable coverage.

For similar reasons, we have changed our position and now believe the individual exemption will not undermine any Government interest in uniformity in the health insurance market. At the level of plan offerings, the extent to which plans cover contraception under the prior rules is already far from uniform. The Congress did not require compliance with section 2713 of the PHS Act by all entities—in particular by grandfathered plans. The Departments' previous exemption for houses of worship and integrated auxiliaries, and our accommodation of self-insured church plans, show that the importance of a uniform health insurance system is not significantly harmed by allowing plans to omit contraception in many contexts.[42]

With respect to operationalizing this provision of these rules, as well as the similar provision protecting individuals with religious objections to purchasing insurance that covers some or all contraceptives, in the interim final rules published elsewhere in this issue of the **Federal Register**, the Departments note that a plan sponsor or health insurance issuer is not required to offer separate and different benefit package options, or separate and different forms of policy, certificate, or contract of insurance with respect to those individuals who object on moral bases from those who object on religious bases. That is, a willing employer or issuer may offer the same benefit package option or policy, certificate, or contract of insurance—which excludes the same scope of some or all contraceptive coverage—to individuals who are exempt from the Mandate because of their moral convictions (under these rules) or their religious beliefs (under the regulations as amended by the interim final rules pertaining to religious beliefs).

7. Optional Accommodation

In addition to expanding the exemption to those with sincerely held moral convictions, these rules also expand eligibility for the optional accommodation process to include employers with objections based on sincerely held moral convictions. This is accomplished by inserting references to the newly added exemption for moral convictions, 45 CFR 147.133, into the regulatory sections where the accommodation process is codified, 45 CFR 147.131, 26 CFR 54.9815–2713AT, and 29 CFR 2590.715–2713A. In all other respects the accommodation process works the same as it does for entities with objections based on sincerely held religious beliefs, as described in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**.

The Departments are not aware of entities with objections to the Mandate based on sincerely held moral convictions that wish to make use of the optional accommodation, and our present assumption is that no such entities will seek to use the accommodation rather than the exemption. But if such entities do wish to use the accommodation, making it available to them will both provide contraceptive coverage to their plan participants and respect those entities' objections. Because entities with objections to the Mandate based on sincerely held non-religious moral convictions have not previously had access to the accommodation, they would not be in a position to revoke their use of the accommodation at the time these interim final rules are issued, but could do so in the future under the same parameters set forth in the accommodation regulations.

8. Regulatory Restatements of Section 2713(a) and (a)(4) of the PHS Act

These interim final rules insert references to 45 CFR 147.133 into the restatements of the requirements of section 2713(a) and (a)(4) of the PHS Act, contained in 26 CFR 54.9815–2713T(a)(1) introductory text and (a)(1)(iv), 29 CFR 2590.715–2713(a)(1) introductory text and (a)(1)(iv), and 45 CFR 147.130(a)(1) and (a)(1)(iv).

9. Conclusion

The Departments believe that the Guidelines, and the expanded exemptions and accommodations set forth in these interim final rules, will advance the legitimate but limited purposes for which Congress imposed section 2713 of the PHS Act, while acting consistently with Congress' well-established record of allowing for moral exemptions with respect to various health care matters. These interim final rules maintain HRSA's discretion to decide whether to continue to require contraceptive coverage under the Guidelines if no regulatorily recognized exemption exists (and in plans where Congress applied section 2713 of the PHS Act). As cited above, these interim final rules also leave fully in place over a dozen Federal programs that provide, or subsidize, contraceptives for women, including for low income women based on financial need. The Departments believe this array of programs and requirements better serves the interests of providing contraceptive coverage while protecting the moral convictions of entities and individuals concerning coverage of some or all contraceptive or sterilization services.

The Departments request and encourage public comments on all matters addressed in these interim final rules.

IV. Interim Final Rules, Request for Comments and Waiver of Delay of Effective Date

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include sections 2701 through 2728 of the PHS Act and the incorporation of those sections into section 715 of ERISA and section 9815 of the Code. These interim final rules fall under those statutory authorized justifications, as did previous rules on this matter (75 FR 41726; 76 FR 46621; and 79 FR 51092).

Section 553(b) of the APA requires notice and comment rulemaking, involving a notice of proposed rulemaking and a comment period prior

196 F. Supp. 3d at 1017, and *March for Life*, 128 F. Supp. 3d at 130—where the courts noted that the individual employee plaintiffs indicated that they viewed the Mandate as pressuring them to "forgo health insurance altogether."

[41] 78 FR 39874.

[42] *See also Real Alternatives*, 2017 WL 3324690 at *36 (3d Cir. Aug. 4, 2017) (Jordan, J., concurring in part and dissenting in part) ("Because insurance companies would offer such plans as a result of market forces, doing so would not undermine the government's interest in a sustainable and functioning market. . . . Because the government has failed to demonstrate why allowing such a system (not unlike the one that allowed wider choice before the ACA) would be unworkable, it has not satisfied strict scrutiny." (citation and internal quotation marks omitted)).

to finalization of regulatory requirements—except when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These provisions of the APA do not apply here because of the specific authority granted to the Secretaries by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act.

Even if these provisions of the APA applied, they would be satisfied: The Departments have determined that it would be impracticable and contrary to the public interest to delay putting these provisions in place until a full public notice-and-comment process is completed. As discussed earlier, the Departments have issued three interim final rules implementing this section of the PHS Act because of the immediate needs of covered entities and the weighty matters implicated by the HRSA Guidelines. As recently as December 20, 2016, HRSA updated those Guidelines without engaging in the regulatory process (because doing so is not a legal requirement), and announced that it plans to so continue to update the Guidelines.

Two lawsuits have been pending for several years by entities raising non-religious moral objections to the Mandate.[43] In one of those cases, the Departments are subject to a permanent injunction and the appeal of that case has been stayed since February 2016. In the other case, Federal district and appeals courts ruled in favor of the Departments, denying injunctive relief to the plaintiffs, and that case is also still pending. Based on the public comments the Departments have received, we have reason to believe that some similar nonprofit entities might exist, even if it is likely a small number.[44]

For entities and individuals facing a burden on their sincerely held moral convictions, providing them relief from Government regulations that impose such a burden is an important and urgent matter, and delay in doing so injures those entities in ways that cannot be repaired retroactively. The burdens of the existing rules undermine these entities' and individuals' participation in the health care market because they provide them with a serious disincentive—indeed a crisis of conscience—between participating in or providing quality and affordable health insurance coverage and being forced to violate their sincerely held moral convictions. The existence of inconsistent court rulings in multiple proceedings has also caused confusion and uncertainty that has extended for several years, with different federal courts taking different positions on whether entities with moral objections are entitled to relief from the Mandate. Delaying the availability of the expanded exemption would require entities to bear these burdens for many more months. Continuing to apply the Mandate's regulatory burden on individuals and organizations with moral convictions objecting to compliance with the Mandate also serves as a deterrent for citizens who might consider forming new entities consistent with their moral convictions and offering health insurance through those entities.

Moreover, we separately expanded exemptions to protect religious beliefs in the companion interim final rules issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. Because Congress has provided many statutes that protect religious beliefs and moral convictions similarly in certain health care contexts, it is important not to delay the expansion of exemptions for moral convictions set forth in these rules, since the companion rules provide protections for religious beliefs on an interim final basis. Otherwise, our regulations would simultaneously provide and deny relief to entities and individuals that are, in the Departments' view, similarly deserving of exemptions and accommodations consistent, with similar protections in other federal laws. This could cause similarly situated entities and individuals to be burdened unequally.

In response to several of the previous rules on this issue—including three issued as interim final rules under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions. Those comments included extensive discussion about whether and to what extent to expand the exemption. Most recently, on July 26, 2016, the Departments issued a request for information (81 FR 47741) and received over 54,000 public comments about different possible ways to resolve these issues. As noted above, the public comments in response to both the RFI and various prior rulemaking proceedings included specific requests that the exemptions be expanded to include those who oppose the Mandate for either religious or "moral" reasons.[45] In connection with past regulations, the Departments have offered or expanded a temporary safe harbor allowing organizations that were not exempt from the HRSA Guidelines to operate out of compliance with the Guidelines. The Departments will fully consider comments submitted in response to these interim final rules, but believe that good cause exists to issue the rules on an interim final basis before the comments are submitted and reviewed. Issuing interim final rules with a comment period provides the public with an opportunity to comment on whether these regulations expanding the exemption should be made permanent or subject to modification without delaying the effective date of the regulations.

As the U.S. Court of Appeals for the D.C. Circuit stated with respect to an earlier IFR promulgated with respect to this issue in *Priests for Life* v. *U.S. Department of Health and Human Services,* 772 F.3d 229, 276 (D.C. Cir. 2014), *vacated on other grounds, Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016), "[S]everal reasons support HHS's decision not to engage in notice and comment here." Among other things, the Court noted that "the agency made a good cause finding in the rule it issued"; that "the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues"; that "HHS will expose its interim rule to notice and comment before its permanent implementation"; and that not proceeding under interim final rules would "delay the implementation of the alternative opt-out for religious objectors." *Id.* at 277. Similarly, not proceeding with exemptions and accommodations for moral objectors here would delay the implementation of those alternative opt-outs for moral objectors.

Delaying the availability of the expanded exemption could also increase the costs of health insurance for some entities. As reflected in litigation pertaining to the Mandate, some entities are in grandfathered health plans that do not cover

[43] *March for Life,* 128 F. Supp. 3d 116; *Real Alternatives,* 867 F.3d 338.

[44] *See, for example,* Americans United for Life ("AUL") Comment on CMA–9992–IFC2 at 10 (Nov. 1, 2011), available at *http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496,* and AUL Comment on CMS–9968–P at 5 (Apr. 8, 2013), available at *http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115.*

[45] *See, for example, http://www.regulations.gov/#!documentDetail;D=HHS-OS-2011-0023-59496, http://www.regulations.gov/#!documentDetail;D=CMS-2012-0031-79115, https://www.regulations.gov/document?D=CMS-2016-0123-54142, https://www.regulations.gov/document?D=CMS-2016-0123-54218,* and *https://www.regulations.gov/document?D=CMS-2016-0123-46220.*

contraception. As such, they may wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status. To the extent that entities with objections to the Mandate based on moral convictions but not religious beliefs fall into this category, they may be refraining from making those changes—and therefore may be continuing to incur and pass on higher insurance costs—to prevent the Mandate from applying to their plans in violation of their consciences. We are not aware of the extent to which such entities exist, but 17 percent of all covered workers are in grandfathered health plans, encompassing tens of millions of people.[46] Issuing these rules on an interim final basis reduces the costs of health insurance and regulatory burdens for such entities and their plan participants.

These interim final rules also expand access to the optional accommodation process for certain entities with objections to the Mandate based on moral convictions. If entities exist that wish to use that process, the Departments believe they should be able to do so without the delay that would be involved by not offering them the optional accommodation process by use of interim final rules. Proceeding otherwise could delay the provision of contraceptive coverage to those entities' employees.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final rules into effect, and that it is in the public interest to promulgate interim final rules. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final rules effective immediately upon filing for public inspection at the Office of the Federal Register.

V. Economic Impact and Paperwork Burden

We have examined the impacts of the interim final rules as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354, section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

A. Executive Orders 12866 and 13563—Department of HHS and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any one year), and an "economically significant" regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below regarding anticipated effects of these rules and the Paperwork Reduction Act, these interim final rules are not likely to have economic impacts of $100 million or more in any one year, and therefore do not meet the definition of "economically significant" under Executive Order 12866. However, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of the Executive Order. Therefore, OMB has reviewed these final regulations and the Departments have provided the following assessment of their impact.

1. Need for Regulatory Action

These interim final rules amend the Departments' July 2015 final regulations and do so in conjunction with the amendments made in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. These interim final rules expand the exemption from the requirement to provide coverage for contraceptives and sterilization, established under the HRSA Guidelines, promulgated under section 2713(a)(4) of the PHS Act, section 715(a)(1) of the ERISA, and section 9815(a)(1) of the Code, to include certain entities and individuals with objections to compliance with the Mandate based on sincerely held moral convictions, and they revise the accommodation process to make entities with such convictions eligible to use it. The expanded exemption would apply to certain individuals, nonprofit entities, institutions of higher education, issuers, and for-profit entities that do not have publicly traded ownership interests, that have a moral objection to providing coverage for some (or all) of the contraceptive and/or sterilization services covered by the Guidelines. Such action is taken, among other reasons, to provide for conscientious participation in the health insurance market free from penalties for violating sincerely held moral convictions opposed to providing or receiving coverage of contraceptive services, to resolve lawsuits that have been filed against the Departments by some such entities, and to avoid similar legal challenges.

2. Anticipated Effects

The Departments acknowledge that expanding the exemption to include objections based on moral convictions might result in less insurance coverage of contraception for some women who may want the coverage. Although the Departments do not know the exact scope of that effect attributable to the moral exemption in these interim final rules, they believe it to be small.

With respect to the expanded exemption for nonprofit organizations, as noted above the Departments are aware of two small nonprofit

[46] Kaiser Family Foundation & Health Research & Educational Trust, "Employer Health Benefits, 2017 Annual Survey," available at *http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017.*

organizations that have filed lawsuits raising non-religious moral objections to coverage of some contraceptives. Both of those entities have fewer than five employees enrolled in health coverage, and both require all of their employees to agree with their opposition to the coverage.[47] Based on comments submitted in response to prior rulemakings on this subject, we believe that at least one other similar entity exists. However, we do not know how many similar entities exist. Lacking other information we assume that the number is small. Without data to estimate the number of such entities, we believe it to be less than 10, and assume the exemption will be used by nine nonprofit entities.

We also assume that those nine entities will operate in a fashion similar to the two similar entities of which we are aware, so that their employees will likely share their views against coverage of certain contraceptives. This is consistent with our conclusion in previous rules that no significant burden or costs would result from exempting houses of worship and integrated auxiliaries. (*See* 76 FR 46625 and 78 FR 39889). We reached that conclusion without ultimately requiring that houses of worship and integrated auxiliaries only hire persons who agree with their views against contraception, and without even requiring that such entities actually oppose contraception in order to be exempt (in contrast, the expanded exemption here requires the exempt entity to actually possess sincerely held moral convictions objecting to the coverage). In concluding that the exemption for houses of worship and integrated auxiliaries would result in no significant burden or costs, we relied on our assumption that the employees of exempt houses of worship and integrated auxiliaries likely share their employers' opposition to contraceptive coverage.

A similar assumption is supported with respect to the expanded exemption for nonprofit organizations. To our knowledge, the vast majority of organizations objecting to the Mandate assert religious beliefs. The only nonprofit organizations of which we are aware that possess non-religious moral convictions against some or all contraceptive methods only hire persons who share their convictions. It is possible that the exemption for nonprofit organizations with moral convictions in these interim final rules could be used by a nonprofit organization that employs persons who do not share the organization's views on contraception, but it was also possible under our previous rules that a house of worship or integrated auxiliary could employ persons who do not share their views on contraception.[48] Although we are unable to find sufficient data on this issue, we believe that there are far fewer non-religious moral nonprofit organizations opposed to contraceptive coverage than there are churches with religious objections to such coverage. Based on our limited data, we believe the most likely effect of the expanded exemption for nonprofit entities is that it will be used by entities similar to the two entities that have sought an exemption through litigation, and whose employees also oppose the coverage. Therefore, we expect that the expanded exemption for nonprofit entities will have no effect of reducing contraceptive coverage to employees who want that coverage.

These interim final rules expand the exemption to include institutions of higher education that arrange student coverage and have non-religious moral objections to the Mandate, and they make exempt entities with moral objections eligible to use the accommodation. The Departments are not aware of either kind of entity. We believe the number of entities that object to the Mandate based on non-religious moral convictions is already very small. The only entities of which we are aware that have raised such objections are not institutions of higher education, and appear to hold objections that we assume would likely lead them to reject the accommodation process. Therefore, for the purposes of estimating the anticipated effect of these interim final rules on contraceptive coverage of women who wish to receive such coverage, we assume that—at this time—no entities with non-religious moral objections to the Mandate will be institutions of higher education that arrange student coverage, and no entities with non-religious moral objections will opt into the accommodation. We wish to make the expanded exemption and accommodation available to such entities in case they do exist or might come into existence, based on similar reasons to those given above for why the exemptions and accommodations are extended to other entities. We invite public comment on whether and how many such entities will make use of these interim final rules.

The expanded exemption for issuers will not result in a distinct effect on contraceptive coverage for women who wish to receive it because that exemption only applies in cases where plan sponsors or individuals are also otherwise exempt, and the effect of those exemptions is discussed elsewhere herein. The expanded exemption for individuals that oppose contraceptive coverage based on sincerely held moral convictions will provide coverage that omits contraception for individuals that object to contraceptive coverage.

The expanded moral exemption would also cover for-profit entities that do not have publicly traded ownership interests, and that have non-religious moral objections to the Mandate. The Departments are not aware of any for-profit entities that possess non-religious moral objections to the Mandate. However, scores of for-profit entities have filed suit challenging the Mandate. Among the over 200 entities that brought legal challenges, only two entities (less than 1 percent) raised non-religious moral objections—both were nonprofit. Among the general public polls vary about religious beliefs, but one prominent poll shows that 89 percent of Americans say they believe in God.[49] Among non-religious persons, only a very small percentage appears to hold moral objections to contraception. A recent study found that only 2 percent of religiously unaffiliated persons believed using contraceptives is morally wrong.[50] Combined, this suggests that 0.2 percent of Americans at most[51] might believe contraceptives are morally wrong based on moral convictions but not religious beliefs. We have no information about how many of those persons run closely held businesses, offer employer sponsored health insurance, and would make use of the expanded exemption for moral

[47] Non-religious nonprofit organizations that engage in expressive activity generally have a First Amendment right to hire only people who share their moral convictions or will be respectful of them—including their convictions on whether the organization or others provide health coverage of contraception, or of certain items they view as being abortifacient.

[48] *Cf., for example*, Gallup, "Americans, Including Catholics, Say Birth Control Is Morally OK," (May 22, 2012) ("Eighty-two percent of U.S. Catholics say birth control is morally acceptable"), available at *http://www.gallup.com/poll/154799/americans-including-catholics-say-birth-control-morally.aspx*.

[49] Gallup, "Most Americans Still Believe in God" (June 14–23, 2016), available at *http://www.gallup.com/poll/193271/americans-believe-god.aspx*.

[50] Pew Research Center, "Where the Public Stands on Religious Liberty vs. Nondiscrimination" at page 26 (Sept. 28, 2016), available at *http://assets.pewresearch.org/wp-content/uploads/sites/11/2016/09/Religious-Liberty-full-for-web.pdf*.

[51] The study defined religiously "unaffiliated" as agnostic, atheist or "nothing in particular" (*id.* at 8), as distinct from several versions of Protestants, or Catholics. "Nothing in particular" might have included some theists.

convictions set forth in these interim final rules. Given the large number of closely held entities that challenged the Mandate based on religious objections, we assume that some similar for-profit entities with non-religious moral objections exist. But we expect that it will be a comparatively small number of entities, since among the nonprofit litigants, only two were non-religious. Without data available to estimate the actual number of entities that will make use of the expanded exemption for for-profit entities that do not have publicly traded ownership interests and that have objections to the Mandate based on sincerely held moral convictions, we expect that fewer than 10 entities, if any, will do so—we assume nine for-profit entities will use the exemption in these interim final rules.

The expanded exemption encompassing certain for-profit entities could result in the removal of contraceptive coverage from women who do not share their employers' views. The Departments used data from the Current Population Survey (CPS) and the Medical Expenditure Panel Survey-Insurance Component (MEPS–IC) to obtain an estimate of the number of policyholders that will be covered by the plans of the nine for-profit entities we assume may make use of these expanded exemptions.[52] The average number of policyholders (9) in plans with under 100 employees was obtained. It is not known what size the for-profit employers will be that might claim this exemption, but as discussed above these interim final rules do not include publicly traded companies (and we invite public comments on whether to do so in the final rules), and both of the two nonprofit entities that challenged the Mandate included fewer than five policyholders in each entity. Therefore we assume the for-profit entities that may claim this expanded exemption will have fewer than 100 employees and an average of 9 policyholders. For nine entities, the total number of policyholders would be 81. DOL estimates that for each policyholder, there is approximately one dependent.[53] This amounts to 162 covered persons. Census data indicate that women of childbearing age—that is, women aged 15–44—comprise 20.2 percent of the general population.[54] This amounts to approximately 33 women of childbearing age for this group of individuals covered by group plans sponsored by for-profit moral objectors. Approximately 44.3 percent of women currently use contraceptives covered by the Guidelines.[55] Thus we estimate that 15 women may incur contraceptive costs due to for-profit entities using the expanded exemption provided in these interim final rules.[56] In the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, we estimate that the average cost of contraception per year per woman of childbearing age that use contraception covered by the Guidelines, within health plans that cover contraception, is $584. Consequently, we estimate that the anticipated effects attributable to the cost of contraception from for-profit entities using the expanded exemption in these interim final rules is approximately $8,760.

The Departments estimate that these interim final rules will not result in any additional burden or costs on issuers or third party administrators. As discussed above, we assume that no entities with non-religious moral convictions will use the accommodation, although we wish to make it available in case an entity voluntarily opts into it in order to allow contraceptive coverage to be provided to its plan participants and beneficiaries. Finally, because the accommodation process was not previously available to entities that possess non-religious moral objections to the Mandate, we do not anticipate that these interim final rules will result in any burden from such entities revoking their accommodated status.

The Departments believe the foregoing analysis represents a reasonable estimate of the likely impact under the rules expanded exemptions. The Departments acknowledge uncertainty in the estimate and therefore conducted a second analysis using an alternative framework, which is set forth in the companion interim final rule concerning religious beliefs issued contemporaneously with this interim final rule and published elsewhere in this issue of the **Federal Register**. Under either estimate, this interim final rule is not economically significant.

We reiterate the rareness of instances in which we are aware that employers assert non-religious objections to contraceptive coverage based on sincerely held moral convictions, as discussed above, and also that in the few instances where such an objection has been raised, employees of such employers also opposed contraception.

We request comment on all aspects of the preceding regulatory impact analysis.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, certain Internal Revenue Service (IRS) regulations, including this one, are exempt from the requirements in Executive Order 12866, as supplemented by Executive Order 13563. The Departments estimate that the likely effect of these interim final rules will be that entities will use the exemption and not the accommodation. Therefore, a regulatory assessment is not required.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public

[52] "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf*Estimates of the number of ERISA Plans based on 2015 Medical Expenditure Survey—Insurance

[53] "Health Insurance Coverage Bulletin" Table 4, page 21. Using March 2015 Annual Social and Economic Supplement to the Current Population Survey. *https://www.dol.gov/sites/default/files/ebsa/researchers/data/health-and-welfare/health-insurance-coverage-bulletin-2015.pdf.*

[54] U.S. Census Bureau, "Age and Sex Composition: 2010" (May 2011), available at *https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf.* The Guidelines' requirement of contraceptive coverage only applies "for all women with reproductive capacity." *https://www.hrsa.gov/womensguidelines/*; *see also* 80 FR 40318. In addition, studies commonly consider the 15–44 age range to assess contraceptive use by women of childbearing age. *See.* Guttmacher Institute, "Contraceptive Use in the United States" (Sept. 2016), available at *https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[55] *See https://www.guttmacher.org/fact-sheet/contraceptive-use-united-states.*

[56] We note that many non-religious for-profit entities which sued the Departments challenging the Mandate, including some of the largest employers, only objected to coverage of 4 of the 18 types of contraceptives required to be covered by the Mandate—namely, those contraceptives which they viewed as abortifacients, and akin to abortion—and they were willing to provide coverage for other types of contraception. It is reasonable to assume that this would also be the case with respect to some for-profits that object to the Mandate on the basis of sincerely held moral convictions. Accordingly, it is possible that even fewer women beneficiaries under such plans would bear out-of-pocket expenses in order to obtain contraceptives, and that those who might do so would bear lower costs due to many contraceptive items being covered.

interest. The interim final rules are exempt from the APA, both because the PHS Act, ERISA, and the Code contain specific provisions under which the Secretaries may adopt regulations by interim final rule and because the Departments have made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the regulations or this amendment would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final rules will have a significant economic effect on a substantial number of small entities. because they will not result in any additional costs to affected entities. Instead, by exempting from the Mandate small businesses and nonprofit organizations with moral objections to some or all contraceptives and/or sterilization, the Departments have reduced regulatory burden on small entities. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

D. Paperwork Reduction Act—Department of Health and Human Services

Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We estimate that these interim final rules will not result in additional burdens not accounted for as set forth in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**. As discussed there, regulations covering the accommodation include provisions regarding self-certification or notices to HHS from eligible organizations (§ 147.131(c)(3)), notice of availability of separate payments for contraceptive services (§ 147.131(f)), and notice of revocation of accommodation (§ 147.131(c)(4)). The burdens related to those ICRs are currently approved under OMB Control Numbers 0938–1248 and 0938–1292. These interim final rules amend the accommodation regulations to make entities with moral objections to the Mandate eligible to use the same accommodation processes. The Departments will update the forms and model notices regarding these processes to reflect that entities with sincerely held moral convictions are eligible organizations.

As discussed above, however, we assume that no entities with non-religious moral objections to the Mandate will use the accommodation, and we know that no such entities were eligible for it until now, so that they do not possess accommodated status to revoke. Therefore we believe that the burden for these ICRs is accounted for in the collection approved under OMB Control Numbers 0938–1248 and 0938–1292, as described in the interim final rules concerning religious beliefs issued contemporaneously with these interim final rules.

We are soliciting comments on all of the possible information collection requirements contained in these interim final rules, including those discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, for which these interim final rules provide eligibility to entities with objections based on moral convictions. In addition, we are also soliciting comments on all of the related information collection requirements currently approved under 0938–1292 and 0938–1248.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of these interim final rules with comment period.

E. Paperwork Reduction Act—Department of Labor

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. In accordance with the requirements of the PRA, the ICR for the EBSA Form 700 and alternative notice have previously been approved by OMB under control numbers 1210–0150 and 1210–0152. A copy of the ICR may be obtained by contacting the PRA addressee shown below or at *http://www.RegInfo.gov.* PRA ADDRESSEE: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue NW., Room N–5718, Washington, DC 20210. Telephone: 202–693–8410; Fax: 202–219–4745. These are not toll-free numbers.

Consistent with the analysis in the HHS PRA section above, although these interim final rules make entities with certain moral convictions eligible for the accommodation, we assume that no entities will use it rather than the exemption, and such entities were not previously eligible for the accommodation so as to revoke it. Therefore we believe these interim final rules do not involve additional burden not accounted for under OMB control number 1210–0150.

Regarding the ICRs discussed in the companion interim final rules concerning religious beliefs issued contemporaneously with these interim final rules and published elsewhere in this issue of the **Federal Register**, the forms for which would be used if any entities with moral objections used the accommodation process in the future, DOL submitted those ICRs in order to obtain OMB approval under the PRA for the regulatory revision. The request was made under emergency clearance procedures specified in regulations at 5 CFR 1320.13. OMB approved the ICRs under the emergency clearance process. In an effort to consolidate the number of information collection requests, DOL indicated it will combine the ICR related to the OMB control number 1210–0152 with the ICR related to the OMB control number 1210–0150. Once

the ICR is approved, DOL indicated it will discontinue 1210–0152. OMB approved the ICR under control number 1210–0150 through [DATE]. A copy of the information collection request may be obtained free of charge on the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201705-1210-001.* This approval allows respondents temporarily to utilize the additional flexibility these interim final regulations provide, while DOL seeks public comment on the collection methods—including their utility and burden. Contemporaneously with the publication of these interim final rules, DOL will publish a notice in the **Federal Register** informing the public of its intention to extend the OMB approval.

F. Regulatory Reform Executive Orders 13765, 13771 and 13777

Executive Order 13765 (January 20, 2017) directs that, "[t]o the maximum extent permitted by law, the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the Act shall exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the Act that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, purchasers of health insurance, or makers of medical devices, products, or medications." In addition, agencies are directed to "take all actions consistent with law to minimize the unwarranted economic and regulatory burdens of the [Affordable Care Act], and prepare to afford the States more flexibility and control to create a more free and open healthcare market." These interim final rules exercise the discretion provided to the Departments under the Affordable Care Act and other laws to grant exemptions and thereby minimize regulatory burdens of the Affordable Care Act on the affected entities and recipients of health care services.

Consistent with Executive Order 13771 (82 FR 9339, February 3, 2017), we have estimated the costs and cost savings attributable to this interim final rule. As discussed in more detail in the preceding analysis, this interim final rule lessens incremental reporting costs.[57] Therefore, this interim final rule is considered an EO 13771 deregulatory action.

G. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (section 202(a) of Pub. L. 104–4), requires the Departments to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $148 million, using the most current (2016) Implicit Price Deflator for the Gross Domestic Product. For purposes of the Unfunded Mandates Reform Act, these interim final rules do not include any Federal mandate that may result in expenditures by State, local, or tribal governments, nor do they include any Federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.

H. Federalism

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on States, the relationship between the Federal Government and States, or the distribution of power and responsibilities among the various levels of Government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

These interim final rules do not have any Federalism implications, since they only provide exemptions from the contraceptive and sterilization coverage requirement in HRSA Guidelines supplied under section 2713 of the PHS Act.

VI. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping

[57] Other noteworthy potential impacts encompass potential changes in medical expenditures, including potential decreased expenditures on contraceptive devices and drugs and potential increased expenditures on pregnancy-related medical services. OMB's guidance on E.O. 13771 implementation (*https://www.whitehouse.gov/the-press-office/2017/04/05/memorandum-implementing-executive-order-13771-titled-reducing-regulation*) states that impacts should be categorized as consistently as possible within Departments. The Food and Drug Administration, within HHS, and the Occupational Safety and Health Administration (OSHA) and Mine Safety and Health Administration (MSHA), within DOL, regularly estimate medical expenditure impacts in the analyses that accompany their regulations, with the results being categorized as benefits (positive benefits if expenditures are reduced, negative benefits if expenditures are raised). Following the FDA, OSHA and MSHA accounting convention leads to this interim final rule's medical expenditure impacts being categorized as (positive or negative) benefits, rather than as costs, thus placing them outside of consideration for E.O. 13771 designation purposes.

requirements, State regulation of health insurance.

Kirsten B. Wielobob,

Deputy Commissioner for Services and Enforcement.

Approved: October 2, 2017.

David J. Kautter,

Assistant Secretary for Tax Policy.

Signed this 4th day of October, 2017.

Timothy D. Hauser,

Deputy Assistant Secretary for Program Operations, Employee Benefits Security Administration, Department of Labor.

Dated: October 4, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 4, 2017.

Donald Wright,

Acting Secretary, Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

For the reasons set forth in this preamble, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ 1. The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

§ 54.9815–2713T [Amended]

■ 2. Section 54.9815–2713T, as added elsewhere in this issue of the **Federal Register**, is amended in paragraph (a)(1)(iv) by removing the reference "147.131 and 147.132" and adding in its place the reference "147.131, 147.132, and 147.133".

§ 54.9815–2713AT [Amended]

■ 3. Section 54.9815–2713AT, as added elsewhere in this issue of the **Federal Register**], is amended—

■ a. In paragraph (a)(1) by removing "or (ii)" and adding in its place "or (ii), or 45 CFR 147.133(a)(1)(i) or (ii)";

■ b. In paragraph (a)(2) by removing the reference "147.132(a)" and adding in its place the reference "147.132(a) or 147.133(a)";

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ d. In paragraph (b)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ f. In paragraph (c)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133"; and

■ g. In paragraph (c)(2) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133".

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Division M, Pub. L. 113–235, 128 Stat. 2130; Secretary of Labor's Order 1–2011, 77 FR 1088 (Jan. 9, 2012).

§ 2590.715–2713 [Amended]

■ 4. Section 2590.715–2713, as amended elsewhere in this issue of the **Federal Register**], is further amended in paragraph (a)(1)(iv) by removing the reference "147.131 and 147.132" and adding in its place the reference "147.131, 147.132, and 147.133".

§ 2590.715–2713A [Amended]

■ 5. Section 2590.715–2713A, as revised elsewhere in this issue of the **Federal Register**], is further amended—

■ a. In paragraph (a)(1) by removing "(ii)" and adding in its place "(ii), or 45 CFR 147.133(a)(1)(i) or (ii)";

■ b. In paragraph (a)(2) by removing the reference "147.132(a)" and adding in its place the reference "147.132(a) or 147.133(a)";

■ c. In paragraph (b)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ d. In paragraph (b)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ e. In paragraph (c)(1)(ii) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133";

■ f. In paragraph (c)(1)(ii)(B) by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133"; and

■ g. In paragraph (c)(2) introductory text by removing the reference "147.132" and adding in its place the reference "147.132 or 147.133".

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR part 147 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 6. The authority citation for part 147 continues to read as follows:

Authority: Secs 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

§ 147.130 [Amended]

■ 7. Section 147.130, as amended elsewhere in this issue of the **Federal Register**, is further amended in paragraphs (a)(1) introductory text and (a)(1)(iv) by removing the reference "§§ 147.131 and 147.132" and adding in its place the reference "§§ 147.131, 147.132, and 147.133".

§ 147.131 [Amended]

■ 8. Section 147.131, as revised elsewhere in this issue of the **Federal Register**, is further amended—

■ a. In paragraph (c)(1) by removing the reference "(ii)" and adding in its place the reference "(ii), or 45 CFR 147.133(a)(1)(i) or (ii)".

■ b. In paragraph (c)(2) by removing the reference "§ 147.132(a)" and adding in its place the reference "§ 147.132(a) or 147.133"; and

■ c. In paragraphs (d)(1)(ii) introductory text, (d)(1)(ii)(B) and (d)(2) by removing the reference "§ 147.132" and to adding in its place the reference "§ 147.132 or 147.133".

■ 9. Add § 147.133 to read as follows:

§ 147.133 Moral exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.* (1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus

the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the extent one of the following non-governmental plan sponsors object as specified in paragraph (a)(2) of this section:

(A) A nonprofit organization; or

(B) A for-profit entity that has no publicly traded ownership interests (for this purpose, a publicly traded ownership interest is any class of common equity securities required to be registered under section 12 of the Securities Exchange Act of 1934);

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under paragraph (a)(1)(iii) of this section, the group health plan established or maintained by the plan sponsor with which the health insurance issuer contracts remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under § 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage or payments for some or all contraceptive services, or for a plan, issuer, or third party administrator that provides or arranges such coverage or payments, based on its sincerely held moral convictions.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate policy, certificate or contract of insurance or a separate group health plan or benefit package option, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held moral convictions.

(c) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

[FR Doc. 2017–21852 Filed 10–6–17; 11:15 am]

BILLING CODE 4830–01–P; 4510–029–P; 4120–01–P; 6325–64–P

Presidential Documents

Executive Order 13798 of May 4, 2017

Promoting Free Speech and Religious Liberty

By the authority vested in me as President by the Constitution and the laws of the United States of America, in order to guide the executive branch in formulating and implementing policies with implications for the religious liberty of persons and organizations in America, and to further compliance with the Constitution and with applicable statutes and Presidential Directives, it is hereby ordered as follows:

Section 1. *Policy.* It shall be the policy of the executive branch to vigorously enforce Federal law's robust protections for religious freedom. The Founders envisioned a Nation in which religious voices and views were integral to a vibrant public square, and in which religious people and institutions were free to practice their faith without fear of discrimination or retaliation by the Federal Government. For that reason, the United States Constitution enshrines and protects the fundamental right to religious liberty as Americans' first freedom. Federal law protects the freedom of Americans and their organizations to exercise religion and participate fully in civic life without undue interference by the Federal Government. The executive branch will honor and enforce those protections.

Sec. 2. *Respecting Religious and Political Speech.* All executive departments and agencies (agencies) shall, to the greatest extent practicable and to the extent permitted by law, respect and protect the freedom of persons and organizations to engage in religious and political speech. In particular, the Secretary of the Treasury shall ensure, to the extent permitted by law, that the Department of the Treasury does not take any adverse action against any individual, house of worship, or other religious organization on the basis that such individual or organization speaks or has spoken about moral or political issues from a religious perspective, where speech of similar character has, consistent with law, not ordinarily been treated as participation or intervention in a political campaign on behalf of (or in opposition to) a candidate for public office by the Department of the Treasury. As used in this section, the term ''adverse action'' means the imposition of any tax or tax penalty; the delay or denial of tax-exempt status; the disallowance of tax deductions for contributions made to entities exempted from taxation under section 501(c)(3) of title 26, United States Code; or any other action that makes unavailable or denies any tax deduction, exemption, credit, or benefit.

Sec. 3. *Conscience Protections with Respect to Preventive-Care Mandate.* The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services shall consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg–13(a)(4) of title 42, United States Code.

Sec. 4. *Religious Liberty Guidance.* In order to guide all agencies in complying with relevant Federal law, the Attorney General shall, as appropriate, issue guidance interpreting religious liberty protections in Federal law.

Sec. 5. *Severability.* If any provision of this order, or the application of any provision to any individual or circumstance, is held to be invalid, the remainder of this order and the application of its other provisions to any other individuals or circumstances shall not be affected thereby.

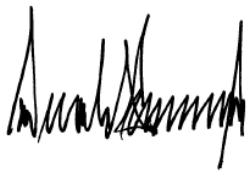
Sec. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
May 4, 2017.

[FR Doc. 2017–09574
Filed 5–8–17; 11:15 am]
Billing code 3295–F7–P

FAQs About Affordable Care Act Implementation Part 36

U.S. Department of Labor
Employee Benefits Security Administration
January 9, 2017

Set out below is an additional Frequently Asked Question (FAQ) regarding implementation of the Affordable Care Act. This FAQ has been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at www.dol.gov/ebsa/healthreform/index.html and www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), this FAQ answers a question from stakeholders to help people understand the law and benefit from it, as intended.

Coverage of Preventive Services

Section 2713 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act and incorporated into the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code (the Code), requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage of certain specified preventive services without cost sharing.

As originally drafted, the bill that became the Affordable Care Act would not have covered additional preventive services that "many women's health advocates and medical professionals believe are critically important" to meeting women's unique health needs. 155 Cong. Rec. 28,841 (2009) (Sen. Boxer). To address that concern, the Senate adopted a "Women's Health Amendment," adding a new category of preventive services specific to women's health. This provision requires coverage without cost sharing of preventive care and screenings for women provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). Supporters of the Women's Health Amendment emphasized that it would reduce unintended pregnancies by ensuring that women receive coverage for "contraceptive services" without cost-sharing. 155 Cong. Rec. at 29,768 (Sen. Durbin).[1]

On August 1, 2011, the Departments issued amended regulations requiring coverage of women's preventive services provided for in the HRSA guidelines,[2] and HRSA adopted and released such guidelines, which were based on recommendations of the independent organization, the National Academy of Medicine (formerly Institute of Medicine).[3] The preventive services identified in the HRSA guidelines include all Food and Drug Administration (FDA)-approved contraceptives, sterilization

[1] *See also*, *e.g.*, 155 Cong. Rec. at 28,841 (Sen. Boxer) ("family planning services"); *id*. at 28,843 (Sen. Gillibrand) ("family planning"); *id*. at 28,844 (Sen. Mikulski) (same); *id*. at 28,869 (Sen. Franken) ("contraception"); *id*. at 29,070 (Sen. Feinstein) ("family planning services"); id. at 29,307 (Sen. Murray) (same).
[2] 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.130.
[3] The 2011 amended regulations were issued and effective on August 1, 2011, and published on August 3, 2011 (76 FR 46621).

procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).[4] Under the regulations issued in August 2011 and the contemporaneously issued HRSA guidelines, group health plans of "religious employers" (organizations that are organized and operate as nonprofit entities and are referred to in section 6033(a)(3)(A)(i) or (iii) of the Code) are exempt from the requirement to provide contraceptive coverage. That exemption reflects "the longstanding governmental recognition of a particular sphere of autonomy for houses of worship." 80 FR 41318, 41325 (July 15, 2015); see 26 U.S.C. 6033(a)(3)(A)(i) or (iii) (referring to "churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order").

Subsequently, on July 2, 2013, the Departments published regulations that provide an accommodation for eligible organizations[5] that object on religious grounds to providing coverage for contraceptive services, but are not eligible for the exemption for religious employers (78 FR 39870).[6] Under the accommodation, an eligible organization is not required to contract, arrange, pay, or provide a referral for contraceptive coverage. At the same time, the accommodation generally ensures that women enrolled in the health plan established by the eligible organization, like women enrolled in health plans maintained by other employers, receive contraceptive coverage seamlessly—that is, through the same issuers or third party administrators that provide or administer the health coverage furnished by the eligible organization, and without financial, logistical, or administrative obstacles.[7] Minimizing such obstacles is essential to achieving the purpose of the Affordable Care Act's preventive services provision, which seeks to remove barriers to the use of preventive services and to ensure that women receive full and equal health coverage appropriate to their medical needs.

In Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014), which addressed claims brought under the Religious Freedom Restoration Act (RFRA), the Supreme Court held that the contraceptive-coverage requirement substantially burdened the religious exercise of the closely held for-profit corporations that had religious objections to providing contraceptive coverage, and that the accommodation was a less restrictive means of providing coverage to their employees. In light of the Hobby Lobby decision, the Departments extended the accommodation to closely held for-profit entities.[8]

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[4] On December 20, 2016, HRSA updated the women's preventive services guidelines, which go into effect for non-grandfathered group health plans and health insurance coverage for plan years (in the individual market, policy years) beginning on or after December 20, 2017. The HRSA guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and male condoms.

[5] An eligible organization, which may seek the accommodation based on its sincerely held religious objection to providing contraceptive coverage, is defined at 26 CFR 54.9815-2713A(a), 29 CFR 2590.715-2713A(a), and 45 CFR 147.131(b),

[6] 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, 45 CFR 147.131.

[7] An accommodation is also available with respect to student health insurance coverage arranged by eligible organizations that are institutions of higher education. 45 CFR 147.131(f). For ease of use, this FAQ refers only to "employers" with religious objections to the contraceptive-coverage requirement, but references to employers with respect to insured group health plans should also be considered to include institutions of higher education that are eligible organizations with respect to student health insurance coverage.

[8] 26 CFR 54.9815-2713A(b)(2)(ii); 29 CFR 2590.715-2713A(b)(2)(ii); 45 CFR. 147.131(b)(2)(ii).

Under the accommodation, an eligible organization that objects to providing contraceptive coverage for religious reasons may either:

> (1) self-certify its objection to its health insurance issuer (to the extent it has an insured plan) or third party administrator (to the extent it has a self-insured plan) using a form provided by the Department of Labor (EBSA Form 700);[9] or
>
> (2) self-certify its objection and provide certain information to HHS without using any particular form.[10]

In *Zubik* v. Burwell, 136 S. Ct. 1557 (2016), the Supreme Court considered claims by a number of employers that, even with the accommodation provided in the regulations, the contraceptive-coverage requirement violates RFRA. Following oral argument, the Court issued an order requesting supplemental briefing from the parties. The Court's order noted that under the existing regulations, an objecting employer with an insured plan that seeks to invoke the accommodation by contacting its issuer must use a form of written notice stating that the employer objects on religious grounds to providing contraceptive coverage.[11] The Court directed the parties to file supplemental briefs addressing "whether contraceptive coverage could be provided to [the objecting employers'] employees, through [the employers'] insurance companies, without any such notice."[12] After consideration of the supplemental briefing, the Supreme Court vacated the judgments of the lower courts and remanded *Zubik* and several other cases raising parallel RFRA challenges to the accommodation. 136 S. Ct. at 1560-1561. The Court emphasized that it "expresse[d] no view on the merits of the cases" and, in particular, that it did not "decide whether [the employers'] religious exercise has been substantially burdened, whether the Government has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest." Id. at 1560. The Court, however, stated that in light of what it viewed as "the substantial clarification and refinement in the positions of the parties" in their supplemental briefs, the parties "should be afforded an opportunity to arrive at an approach going forward that accommodates [the objecting employers'] religious exercise while at the same time ensuring that women covered by [the employers'] health plans 'receive full and equal health coverage, including contraceptive coverage.'" Id. (citation omitted).[13]

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[9] The EBSA Form 700 serves as a certification that the organization is an "eligible organization" (as described in 26 CFR 54.9815-2713A(a), 29 CFR 2590.715-2713A(a), and 45 CFR 147.131(b)) that has a religious objection to providing coverage for some or all of any contraceptive services that would otherwise be required to be covered. The EBSA Form 700 is available at: **https://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf**.

[10] A model notice to HHS that eligible organizations may use, but are not required to use, is available at: **http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Prevention**.

[11] *Zubik v. Burwell*, Nos. 14-1418 et al., 2016 WL 1203818, at *2 (Mar. 29, 2016).

[12] *Id.*

[13] The Supreme Court specified that, while the RFRA litigation remains pending, "the Government may not impose taxes or penalties on [the plaintiffs] for failure to provide the … notice" required under the existing accommodation regulations. *Zubik*, 136 S. Ct. at 1561. At the same time, the Court also emphasized that "[n]othing in [its] opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by [plaintiffs'] health plans 'obtain, without cost, the full range of FDA approved contraceptives.'" *Id.* at 1560-1561 (quoting *Wheaton College v. Burwell*, 134 S. Ct. 2806, 2807 (2014)).

On July 22, 2016, the Departments published a request for information (RFI) (81 FR 47741) seeking input from interested parties to determine, as contemplated by the Supreme Court's opinion in *Zubik*, whether modifications to the existing accommodation procedure could resolve the objections asserted by the plaintiffs in the pending RFRA cases, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.

The Departments explained that they were using the RFI procedure because the issues addressed in the supplemental briefing in *Zubik* affect a wide variety of stakeholders, including many who are not parties to the cases that were before the Supreme Court. Other employers also have brought RFRA challenges to the accommodation, and their views may differ from the views held by the employers in *Zubik* and the consolidated cases. In addition, any change to the accommodation could have implications for the rights and obligations of issuers, group health plans, third party administrators, and women enrolled in health plans established by objecting employers. The RFI was intended to assist the Departments in determining whether there are modifications to the accommodation that would be available under current law and that could resolve the pending RFRA claims brought by objecting organizations. The Departments sought feedback from all interested stakeholders, including objecting organizations, and specifically requested that such organizations address the particular issues outlined in the RFI.

In response to the RFI, the Departments received over 54,000 public comments by the comment closing date of September 20, 2016. Commenters included the plaintiffs in *Zubik* and other religiously affiliated organizations, consumer advocacy groups, women's organizations, health insurance issuers, third party administrators and pharmaceutical benefit managers, other industry representatives, employers, members of the public, and other interested stakeholders.[14] The Departments are issuing this FAQ after consideration of comments submitted by a broad array of stakeholders, including the *Zubik* plaintiffs and similar religious organizations, issuers or third party administrators, and commenters representing women's and consumer advocacy organizations.

Q: ARE THE DEPARTMENTS MAKING CHANGES TO THE ACCOMMODATION AT THIS TIME?

No. As described in more detail below, the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage. The comments demonstrate that a process like the one described in the Court's supplemental briefing order would not be acceptable to those with religious objections to the contraceptive-coverage requirement. Further, a number of comments illustrate that the administrative and operational challenges to a process like the one described in the Court's order are more significant than the Departments had previously understood and would potentially undermine women's access to full and equal coverage. For these reasons, the Departments are not modifying the accommodation regulations at this time.

As the government explained in its briefs in *Zubik*, the Departments continue to believe that the existing accommodation regulations are consistent with RFRA for two independent reasons. First, as eight of the nine courts of appeals to consider the issue have held, by virtue of objecting employers'

[14] The public comments are accessible at **https://www.regulations.gov/docket?D=CMS-2016-0123**.

ability to avail themselves of the accommodation, the contraceptive-coverage requirement does not substantially burden their exercise of religion. Second, as some of those courts have also held, the accommodation is the least restrictive means of furthering the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage.

NOTIFICATION TO ISSUERS WITHOUT SELF-CERTIFICATION

In its request for supplemental briefing in *Zubik*, the Supreme Court asked the parties to address "whether and how contraceptive coverage may be obtained by [objecting employers'] employees through [the employers'] insurance companies, but in a way that does not require any involvement of [the employers] beyond their own decision to provide health insurance without contraceptive coverage to their employees."[15] Specifically, the Court described—

> a situation in which [objecting employers] would contract to provide health insurance for their employees, and in the course of obtaining such insurance, inform their insurance company that they do not want their health plan to include contraceptive coverage of the type to which they object on religious grounds. [The employers] would have no legal obligation to provide such contraceptive coverage, would not pay for such coverage, and would not be required to submit any separate notice to their insurer, to the Federal government, or to their employees. At the same time, [the employers'] insurance compan[ies]—aware that [the employers] are not providing certain contraceptive coverage on religious grounds—would separately notify [the employers'] employees that the insurance company will provide cost-free contraceptive coverage, and that such coverage is not paid for by [the employers] and is not provided through [the employers'] health plan[s].[16]

The Departments sought comments on whether this alternative would be acceptable to objecting organizations, and if not, whether further procedures or systems could resolve their RFRA concerns. The Departments asked if organizations specifically object on RFRA grounds to informing their issuers that they object to contraceptive coverage "on religious grounds," or to a requirement that the request by an eligible organization to its issuer be made in writing or through use of a particular form. The Departments also sought comments on whether it would be feasible for issuers to implement the accommodation without the written notification requirement and what effect this alternative procedure would have on the access of women to seamless contraceptive coverage.

In light of the comments received, the Departments have determined not to amend the regulations at this time. On the one hand, comments from parties before the Supreme Court (and other objecting employers) do not suggest that the change identified by the Supreme Court would resolve their concerns. On the other hand, the Departments received comments stating that eliminating written notification would create significant administrative problems and potential legal liabilities for issuers, and would hinder women's access to care. As described in greater detail below, these comments

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[15] *Zubik*, 2016 WL 1203818, at *2.
[16] *Id.*

have shown that the elimination of the written notification requirement would raise complications that would undermine the statute's goal of ensuring full and equal health coverage for women, the extent of which were not known to the Departments at the time the government filed its supplemental briefs in *Zubik*.

First, comments on behalf of issuers stated that eliminating written notifications would impose administrative costs by forcing them to create new systems to distinguish and track different employers, employees, and the coverage to be provided.[17] For example, commenters stated that issuers currently rely on the written notifications to track the differences between eligible organizations that are seeking an accommodation due to their religious objections -- organizations that the Supreme Court has said are "effectively exempt" from the contraceptive-coverage requirement -- and religious employers that are automatically exempt under the HRSA guidelines. These comments asserted that eliminating written notifications would burden issuers with creating new systems to distinguish and track these two categories of employers.

Given the different ways in which issuers must treat and respond to these two types of entities, the Departments understand that issuers must be able to easily and separately track the coverage issued to the plans sponsored by these different organizations. With respect to exempt organizations, issuers merely need to eliminate contraceptive benefits from the group health insurance policy. However, with respect to eligible organizations that avail themselves of the accommodation, issuers must take the additional step of making separate payments for contraceptive services, along with providing notice of the availability of such payments. Furthermore, some eligible organizations may object to covering all forms of contraceptive services in their group health coverage while others may object only to certain types of contraceptive services. The Departments conclude therefore that written notification from employers significantly improves issuers' ability to appropriately identify and administer coverage for each of these two categories of employers. The commenters also said that issuers might be subject to legal risks if written notification were eliminated, because they would have no written record to demonstrate compliance with applicable law and regulations to the extent they relied on an organization's oral representation of its eligibility for the accommodation that was later determined to be incorrect. Such legal risks would be magnified, according to the commenters, in circumstances in which issuers would have to rely on agents and brokers to verify eligibility.

Based on these concerns, comments indicated that, even without a legal requirement to use a required form, issuers would likely seek written documentation, such as an attestation, from objecting employers to confirm the employer's eligibility as a condition of administering the accommodation. For example, an issuer might demand written documentation as a pre-condition for entering into a contract with an organization seeking the accommodation. The commenters indicated that if the written notification requirement were eliminated, employers might object to providing this type of verification, which is currently commonplace for certain purposes, such as communicating grandfathered status. The Departments note that, under the current accommodation,

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[17] Related to these comments with respect to the administrative costs of distinguishing and tracking different coverage to be provided, the Departments note that an eligible organization may seek an accommodation so that it need not contract, arrange, pay, or provide a referral for *all* otherwise required contraceptive services, or any subset of such services. Thus, there could be many different combinations of contraceptive services that an issuer must cover, and within each such combination, some such benefits must be provided by the group health insurance policy, and others for which the issuer must make separate payments.

once an issuer has been provided the documentation specified in the accommodation regulations, it may not require any further documentation from an eligible organization regarding its status as such.[18]

Second, several commenters suggested that the lack of written notice would create confusion and miscommunication, which in turn would lead to disputes between the parties, billing problems, and reduced access to care for women. For example, comments from women's advocacy organizations stated that lack of written notice could have repercussions for processing payments to a provider. This could disrupt continuity of care and burden women seeking to resolve any miscommunication between the objecting entity and the issuer. Further, according to these commenters, it could also impose the additional burden of affected women having to affirmatively assert their eligibility in situations where an employer has not timely provided its oral objection.

One commenter stated that, without a written notification, an eligible employer's representative may misstate an employer's wishes or incorrectly assert eligibility for the accommodation, resulting in a dispute that delays the process of arranging contraceptive coverage for women.

Several commenters representing women's and consumer advocacy organizations stressed the importance of written documentation for verifying compliance and ensuring that women are able to obtain direct, continuous access to the full range of contraceptive methods without cost. These commenters also suggested that eliminating written documentation could hamper the Departments' oversight and enforcement efforts.

Third, as noted above, the Departments have not identified any comments from objecting employers, including any of the *Zubik* plaintiffs, stating that eliminating the written notification requirement would be sufficient to satisfy their RFRA concerns. For example, one comment indicate that employers would object to "any requirement . . . that has the purpose or effect of providing access to or increasing the use of contraceptive services."

The Departments agree that written documentation establishing that a given employer requested the accommodation, and that it satisfies the definition of an eligible organization, is of value to document the legal responsibilities and rights of employees, issuers, and beneficiaries, as well as to minimize the number of disputes between employers and issuers regarding the accommodation. In turn, the Departments conclude that, by minimizing such disputes and providing certainty regarding which organizations have and have not requested the accommodation, the written notice requirement minimizes the potential number of employers that will be in violation of the contraceptive-coverage requirement. By helping to define which organizations have and have not availed themselves of the accommodation, written documentation also ensures that women receive timely access to contraceptive coverage, as it will help issuers to quickly and effectively determine the appropriate source of payment for such services, i.e., payment through the group health insurance policy, or separate payment for contraceptive services. And as the government explained in its Supreme Court briefs, the regulatory requirement for eligible organizations to provide written notification of their objection is consistent with RFRA.

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[18] 26 CFR 54.8815-2713A(c)(1)(i), 29 CFR 2590.715-2713A(c)(1)(i), 45 CFR 147.131(c)(1)(i).

OTHER APPROACHES WITH RESPECT TO INSURED PLANS DESCRIBED IN THE SUPPLEMENTAL BRIEFING

The *Zubik* plaintiffs proposed that when an eligible employer with an insured plan requests insurance coverage that excludes contraceptive coverage to which it objects on religious grounds, the employer's issuer should be required to provide the required coverage through separate insurance policies that cover only contraceptives and in which women should have to affirmatively enroll. Pet. Supp. Br. 3-12.[19] The Departments sought comments on whether this alternative procedure would resolve the RFRA claims of objecting organizations; whether it would be feasible for health insurance issuers and consistent with State insurance laws; what effect this approach would have on the ability of women enrolled in group health plans established by objecting employers to obtain seamless coverage for contraceptive services; and whether there might be alternatives other than contraceptive-only policies or affirmative enrollment requirements that would resolve the RFRA objections of objecting organizations.

In response to the RFI, objecting employers argued that to be truly independent, contraceptive coverage must be provided to women enrolled in health plans of objecting employers through separate insurance policies. The Departments identified no comments indicating that eliminating written notification by itself would be sufficient. In fact, several commenters stated that, even if the government were to eliminate the written notice requirement, the accommodation would have to be modified in other ways to satisfy their concerns. One commenter, quoting from the petitioners' brief in *Zubik*, stated that there must be an enrollment process that is distinct from (and not an automatic consequence of) enrolling in the employer's plan. Another commenter stated that the issuer or third party administrator should be required to provide eligible participants and beneficiaries with a separate enrollment card for contraceptive coverage that would require activation by each participant or beneficiary. The commenter stated that this should replace the current requirement that participants automatically receive coverage for contraceptive services. (For further discussion of this issue, see section below titled "Separate Enrollment Cards and Activation.")

A number of commenters emphasized the significant problems posed by requiring separate contraceptive-only coverage. Commenters identified several obstacles under State contract and insurance law. Comments submitted on behalf of issuers asserted that some State insurance regulators do not have authority under State law to approve single-benefit policies (other than dental or vision). The commenters also explained that cost-free contraception policies would not satisfy laws conditioning policy approval on a "reasonable premium" or constitute valid contracts because the prospective policyholder would not provide consideration. In addition, they commented that under State licensure laws, issuers that sell group coverage could not offer contraceptive-only policies to individual women because they are not licensed to offer coverage in the individual market and that State laws would prevent issuers licensed to issue group coverage in one State from issuing individual policies to employees of an eligible organization residing in other States.

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[19] As of the date of publication of this FAQ, petitioners' supplemental brief is available at **http://www.scotusblog.com/wp-content/uploads/2016/04/Non-profits-response-to-Zubik-order-4-12-16.pdf**. Petitioners' supplemental reply brief is available at **http://www.scotusblog.com/wp-content/uploads/2016/04/Zubik-order-non-profits-reply-brief-4-20-161.pdf**.

In addition, several commenters stated that separate contraceptive coverage policies may have a different provider network from that of the group health plan that provides the women's other health benefits, which would mean that the separate contraceptive policies would not necessarily include women's regular doctors. One commenter stated that it would be costly and administratively burdensome for issuers to develop and implement new eligibility, enrollment, and claims-adjudication systems for contraception-only coverage, as they would differ from their existing systems. Several commenters also maintained that requiring women to seek out separate contraceptive coverage would create the same barriers in access that the Affordable Care Act's preventive services provision was designed to eliminate. The Departments agree these approaches would potentially undermine women's access to full and equal coverage, contrary to the statutory objective of reducing barriers to the use of important preventive services.

SELF-INSURED PLANS

The Supreme Court's supplemental briefing order in *Zubik* addressed only employers with "insured plans."[20] In its supplemental brief, the government described the operation of the accommodation for self-insured plans and explained that an alternative process like the one the Court posited for insured plans could not work for the many employers with self-insured plans:

> If an employer has a self-insured plan, the statutory obligation to provide contraceptive coverage falls only on the plan—there is no insurer with a preexisting duty to provide coverage. Accordingly, to relieve self-insured employers of any obligation to provide contraceptive coverage while still ensuring that the affected women receive coverage without the employer's involvement, the accommodation establishes a mechanism for the government to designate the employer's TPA [third party administrator] as a 'plan administrator' responsible for separately providing the required coverage under [ERISA]. That designation is made by the government, not the employer, and the employer does not fund, control, or have any other involvement with the separate portion of the ERISA plan administered by the TPA.
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> The government's designation of the TPA must be reflected in a written plan instrument. To satisfy that requirement, the accommodation relies on either (1) a written designation sent by the government to the TPA, which requires the government to know the TPA's identity, or (2) the self-certification form, which the regulations treat as a plan instrument in which the government designates the TPA as a plan administrator. There is no mechanism for requiring TPAs to provide separate contraceptive coverage without a plan instrument; self-insured employers could not opt out of the contraceptive-coverage requirement by simply informing their TPAs that they do not want to provide coverage for contraceptives. Gov't Supp. Br. 16-17 (citations omitted).

[20] *Zubik*, 2016 WL 1203818, at *2.

The *Zubik* plaintiffs also stated that an arrangement like the one posited in the Supreme Court's briefing order for insured plans could not work for self-insured plans. See Pet. Supp. Br. 16-17.

The RFI sought comment on any possible modifications to the current accommodation for self-insured plans, including self-insured church plans, which would resolve objecting organizations' RFRA objections while still providing women full and equal access to coverage. Specifically, the RFI asked whether there are any reasonable alternative means available under existing law by which the Departments could ensure that women enrolled in self-insured plans maintained by objecting employers receive separate contraceptive coverage that is not contracted, arranged, paid, or referred for by the objecting organization but that is provided through the same third party administrators that administer the rest of their health benefits.

The Departments did not identify any comments in response to the RFI that described a feasible pathway for oral notification to third party administrators with respect to self-insured plans to allow full and equal provision of contraceptive services to the women enrolled in those plans.

Some commenters noted that third party administrators often do not require separate notification, written or oral, that a self-insured plan will not be providing contraceptive coverage because other documentation, such as summary plan descriptions or provider contracts, will indicate that such coverage is not provided under the plan. However, without a written plan instrument, which is provided for in the current accommodation, there is no mechanism to designate a third party administrator as the ERISA plan administrator for purposes of arranging or providing separate payments for contraceptive services.

Many commenters suggested that cost-free contraception should be provided by the federal government through mechanisms that differ substantially from the procedure for insured plans described in the Supreme Court's supplemental briefing order. For example, some commenters suggested that for those self-insured plans that have third party administrators that are not able to provide separate cost-free contraceptive coverage to covered employees, the objecting employer could simply inform such third party administrators of the employer's objection and the government would "exempt" such self-insured plans and third party administrators from the requirement to provide separate cost-free contraceptive coverage. In those cases, commenters proposed that the government could provide coverage by having the employer notify HHS that the employer will not provide coverage and HHS would then coordinate with IRS to determine the identity of that employer's employees through W-2 or other tax information otherwise supplied by the objecting employer. These commenters suggest that such a program could be paid for by using credits against Federally-facilitated Exchange (FFE) user fees (which are already being used for the existing accommodation).

One commenter asserted that the federal government could directly subsidize the cost of purchasing contraceptive items and services for those employees who participate in an eligible organization's group health plan. However, as the Departments have previously indicated in rulemaking in response to comments suggesting that the government reimburse plan participants for the costs of contraceptive services,[21] and in its briefs to the Supreme Court, this approach raises legal and

[21] 80 FR 41317, 41328 (July 14, 2015).

practical obstacles to access to seamless coverage. Consistent with the statutory objective of promoting access to preventive services, such as contraceptive coverage, without cost-sharing, plan participants and beneficiaries should not be required to incur additional costs or burdens to receive access. Therefore, they should not be required to enroll in new programs or to surmount other hurdles to receive access to coverage.

SEPARATE ENROLLMENT CARDS AND ACTIVATION

As stated above, several objecting organizations have suggested that some of their objections to the accommodation could be alleviated by providing a separate enrollment card for contraceptive coverage. Under this approach, women would not enroll in a separate insurance policy for contraceptive coverage, but would receive a separate enrollment card that would be automatically activated only when a woman who is enrolled in the group health plan attempts to obtain contraceptive benefits.

If objecting employers prefer the use of a separate enrollment card for contraceptive coverage, the Departments note that under the current accommodation regulations, issuers or third party administrators could provide a separate enrollment card for contraceptive coverage. The current regulations do not specify the manner in which an issuer or third party administrator provides "enrollment cards" or other means of providing similar, relevant information to enrollees, as long as the manner in which the card or other information is provided does not unduly inhibit or hamper access to the benefit. See 29 CFR 2560.503-1, which is applicable to ERISA plans and incorporated in 26 CFR 54.9815-2719(b)(2)(i), 29 CFR 2590.715-2719(b)(2)(i), and 45 CFR 147.136(b)(2)(i), which are applicable to non-grandfathered health plans and coverage. As stated above, under current rules, the issuer or third party administrator could provide a separate enrollment card for contraceptive coverage.[22] The card could bear a different design to distinguish it from enrollment cards used to access services covered by the employer's group health plan, and could omit the name of the employer and/or the plan as well. The card could use the same identification number as is used on the enrollment card for services covered by the group health plan, or could have a different number provided there is a mechanism in place (such as by linking the two numbers in the issuer's or third party administrator's processing systems) that enables the issuer or third party administrator to easily identify enrollees. The foregoing arrangements are permissible if they are not used as an impediment to obtaining benefits and do not unduly inhibit or hamper a plan participant or beneficiary from accessing benefits provided pursuant to the accommodation (e.g., a plan procedure providing for the denial of benefits based on failure to present or "activate" the enrollment card or "opt in," even when the provider has otherwise verified participant status).

[22] *Id.*

Abstract: Currently HRSA is cleared to use the National Institutes of Health's (NIH) Biographical Sketch and Public Health Service (PHS) Inclusion Enrollment forms (0925–0001) for HRSA's SF424 Research & Related (R&R) application package research grants. However, both of these documents contain NIH-specific references. To use the forms, HRSA plans to remove the NIH-specific references and obtain its own OMB control number for the collection of this information.

The current Statement of Appointment (form PHS–2271) is also tailored to NIH programs. HRSA plans to remove references to NIH and where appropriate replace them with references to HRSA for use in the SF424 R&R application package.

Need and Proposed Use of the Information: Currently, there are two Bureaus within HRSA, the Maternal and Child Health Bureau (MCHB) and the Bureau of Health Workforce (BHW), that use the Biographical Sketch. In addition to the Biographical Sketch, MCHB also uses the PHS Inclusion Enrollment form, and BHW uses the Statement of Appointment form as required elements of the SF424 Research & Related application package. These Bureaus plan to modify these forms in slightly different ways to meet the needs of their own research and training grant programs.

In MCHB's research grant programs, the modified Biographical Sketch form will be used by applicants to summarize the qualifications of key personnel on their proposed research team; the grant reviewers will use this information to assess the capabilities of the research team to carry out the research project. MCHB's modified PHS Inclusion Enrollment form will be used by applicants to summarize their expected population of research study participants at the time of submission of their proposal; it will also be used for Enrollment Reporting during the annual Noncompeting Continuation Award. Monitoring Inclusion Enrollment is one important component of ensuring statistically meaningful demographics (race, ethnicity, and gender) among research study participants in MCHB's research grant portfolio. MCHB does not use the Statement of Appointment form, as it does not pertain to the MCHB research program.

Similarly, in BHW the modified Biographical Sketch form will be used by applicants to summarize the qualifications of key personnel proposed as project staff; the grant reviewers will use this information to assess the capabilities of the applicant organization to carry out the proposed project. The modified Statement of Appointment form is used to document the appointment of individuals supported by the award to applicable institutional research and training programs. BHW does not use the PHS Inclusion Enrollment form, as it does not pertain to the BHW training and research programs.

Likely Respondents: Respondents are applicants to HRSA's research programs in MCHB and research and training programs in BHW.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Biographical Sketch for MCHB research grant applicants ..	200	5	1000	2	2000
PHS Inclusion Enrollment form for MCHB research grant applications	200	1	200	.5	100
Biographical Sketch for BHW training and research grant applicants	1000	5	5000	2	10,000
Statement of Appointment form for BHW training grantees	800	7	5600	.5	2,800
Total	2200	.....	11,800	.....	14,900

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–31080 Filed 12–23–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Updating the HRSA-Supported Women's Preventive Services Guidelines

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: Effective December 20, 2016, the Health Resources and Services Administration (HRSA) updated the HRSA-supported Women's Preventive Services Guidelines for purposes of health insurance coverage for preventive services that address health needs specific to women based on clinical recommendations from the Women's Preventive Services Initiative. This notice serves as an announcement of the decision to update the guidelines as listed below. Please see *https://www.hrsa.gov/womensguidelines2016* for additional information.

FOR FURTHER INFORMATION CONTACT: HRSA, Maternal and Child Health Bureau at email: *wellwomancare@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Breast Cancer Screening for Average-Risk Women

The Women's Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Breastfeeding Services and Supplies

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

Screening for Cervical Cancer

The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.

Contraception

The Women's Preventive Services Initiative recommends that adolescent and adult women have access to the full range of female-controlled contraceptives to prevent unintended pregnancy and improve birth outcomes. Contraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care (*e.g.,* management, and evaluation as well as changes to and removal or discontinuation of the contraceptive method). The Women's Preventive Services Initiative recommends that the full range of female-controlled U.S. Food and Drug Administration-approved contraceptive methods, effective family planning practices, and sterilization procedures be available as part of contraceptive care.

The full range of contraceptive methods for women currently identified by the U.S. Food and Drug Administration include: (1) Sterilization surgery for women, (2) surgical sterilization via implant for women, (3) implantable rods, (4) copper intrauterine devices, (5) intrauterine devices with progestin (all durations and doses), (6) the shot or injection, (7) oral contraceptives (combined pill), 8) oral contraceptives (progestin only, and), (9) oral contraceptives (extended or continuous use), (10) the contraceptive patch, (11) vaginal contraceptive rings, (12) diaphragms, (13) contraceptive sponges, (14) cervical caps, (15) female condoms, (16) spermicides, and (17) emergency contraception (levonorgestrel), and (18) emergency contraception (ulipristal acetate), and additional methods as identified by the FDA. Additionally, instruction in fertility awareness-based methods, including the lactation amenorrhea method, although less effective, should be provided for women desiring an alternative method.

Screening for Gestational Diabetes Mellitus

The Women's Preventive Services Initiative recommends screening pregnant women for gestational diabetes mellitus after 24 weeks of gestation (preferably between 24 and 28 weeks of gestation) in order to prevent adverse birth outcomes. Screening with a 50-g oral glucose challenge test (followed by a 3-hour 100-g oral glucose tolerance test if results on the initial oral glucose challenge test are abnormal) is preferred because of its high sensitivity and specificity.

The Women's Preventive Services Initiative suggests that women with risk factors for diabetes mellitus be screened for preexisting diabetes before 24 weeks of gestation—ideally at the first prenatal visit, based on current clinical best practices.

Screening for Human Immunodeficiency Virus Infection

The Women's Preventive Services Initiative recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All women should be tested for HIV at least once during their lifetime. Additional screening should be based on risk, and screening annually or more often may be appropriate for adolescents and women with an increased risk of HIV infection.

Screening for HIV is recommended for all pregnant women upon initiation of prenatal care with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with an undocumented HIV status. Screening during pregnancy enables prevention of vertical transmission.

Screening for Interpersonal and Domestic Violence

The Women's Preventive Services Initiative recommends screening adolescents and women for interpersonal and domestic violence, at least annually, and, when needed, providing or referring for initial intervention services. Interpersonal and domestic violence includes physical violence, sexual violence, stalking and psychological aggression (including coercion), reproductive coercion, neglect, and the threat of violence, abuse, or both. Intervention services include, but are not limited to, counseling, education, harm reduction strategies, and referral to appropriate supportive services.

Counseling for Sexually Transmitted Infections

The Women's Preventive Services Initiative recommends directed behavioral counseling by a health care provider or other appropriately trained individual for sexually active adolescent and adult women at an increased risk for sexually transmitted infections (STIs).

The Women's Preventive Services Initiative recommends that health care providers use a woman's sexual history and risk factors to help identify those at an increased risk of STIs. Risk factors may include age younger than 25, a recent history of an STI, a new sex partner, multiple partners, a partner with concurrent partners, a partner with an STI, and a lack of or inconsistent condom use. For adolescents and women not identified as high risk, counseling to reduce the risk of STIs should be considered, as determined by clinical judgement.

Well-Woman Preventive Visits

The Women's Preventive Services Initiative recommends that women receive at least one preventive care visit per year beginning in adolescence and continuing across the lifespan to ensure that the recommended preventive services including preconception, and many services necessary for prenatal and interconception care are obtained. The primary purpose of these visits

should be the delivery and coordination of recommended preventive services as determined by age and risk factors.

The HRSA-supported Women's Preventive Services Guidelines were originally established in 2011 based on recommendations from a Department of Health and Human Services' commissioned study by the Institute of Medicine (IOM), now known as the National Academy of Medicine (NAM). Since then, there have been advancements in science and gaps identified in the existing guidelines, including a greater emphasis on practice-based clinical considerations. To address these, HRSA awarded a 5-year cooperative agreement in March 2016 to convene a coalition of clinician, academic, and consumer-focused health professional organizations and conduct a scientifically rigorous review to develop recommendations for updated Women's Preventive Services Guidelines in accordance with the model created by the NAM *Clinical Practice Guidelines We Can Trust.* The American College of Obstetricians and Gynecologists was awarded the cooperative agreement and formed an expert panel called the Women's Preventive Services Initiative.

Under section 2713 of the Public Health Service Act, non-grandfathered group health plans and issuers of non-grandfathered group and individual health insurance coverage are required to cover specified preventive services without a copayment, coinsurance, deductible, or other cost sharing, including preventive care and screenings for women as provided for in comprehensive guidelines supported by HRSA for this purpose. Non-grandfathered plans and coverage (generally, plans or policies created or sold after March 23, 2010, or older plans or policies that have been changed in certain ways since that date) are required to provide coverage without cost sharing consistent with these guidelines beginning with the first plan year (in the individual market, policy year) that begins on or after December 20, 2017.

The guidelines concerning contraceptive methods and counseling do not apply to women who are participants or beneficiaries in group health plans sponsored by religious employers. Effective August 1, 2013, a religious employer is defined as an employer that is organized and operates as a non-profit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code. HRSA notes that, as of August 1, 2013, group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services under section 2713 of the Public Health Service Act, as incorporated into the Employee Retirement Income Security Act and the Internal Revenue Code. HRSA also notes that, as of January 1, 2014, accommodations are available to group health plans established or maintained by certain eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations, with respect to the contraceptive coverage requirement. See Coverage of Certain Preventive Services Under the Affordable Care Act (78 FR 39870, July 2, 2013).

James Macrae,

Acting Administrator.

[FR Doc. 2016–31129 Filed 12–23–16; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Announcement of Updated Requirements and Registration for "The Simple Extensible Sampling Tool Challenge"

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: On September 29, 2016, OIG announced ''The Simple Extensible Sampling Tool Challenge''. This notice serves as an update to the original notice which stated that upon receipt of an updated submission the previous submission would be excluded in its entirety from the competition. This updated notice removes this restriction for entries from teams that have been previously identified as finalists. Any finalist may update their entry without losing their finalist designation. Updates from the finalists will be accepted until 5:00 p.m. EST on the fourteenth day after the fifth finalist has been identified or May 15, 2017, 5:00 p.m. EST, whichever comes first. The newest entry from each team will be used for all judging purposes unless otherwise requested by the team. Other than the above change, all rules and requirements outlined in the September 29, 2016, **Federal Register** notice remain in effect.

Dated: December 21, 2016.

Daniel R. Levinson,

Inspector General.

[FR Doc. 2016–31182 Filed 12–23–16; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the Council of Councils.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov*).

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Council of Councils.

Open: January 27, 2017.

Time: 8:15 a.m. to 11:30 a.m.

Agenda: Call to Order and Introductions; Announcements and Updates; Tracking Utility of Common Fund Data Sets; Small Molecules from the Human Microbiota; Invited Speaker; NIH Update; Discussion; 2017 Biennial Advisory Council Report—Compliance with the NIH Policy on the Inclusion of Women and Minorities in Clinical Research.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Closed: January 27, 2017.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: Review of grant applications.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Open: January 27, 2017.

elsewhere in this issue of the **Federal Register**].

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2016–16561 Filed 7–21–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 147

[CMS–9931–NC]

Coverage for Contraceptive Services

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: This document is a request for information on whether there are alternative ways (other than those offered in current regulations) for eligible organizations that object to providing coverage for contraceptive services on religious grounds to obtain an accommodation, while still ensuring that women enrolled in the organizations' health plans have access to seamless coverage of the full range of Food and Drug Administration-approved contraceptives without cost sharing. This information is being solicited in light of the Supreme Court's opinion in *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016). The Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) invite public comments via this request for information.

DATES: Comments must be submitted on or before September 20, 2016.

ADDRESSES: In commenting, please refer to file code CMS–9931–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9931–NC, P.O. Box 8010, Baltimore, MD 21244–8010. Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–9931–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: David Mlawsky, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, at (410) 786–1565.

Elizabeth Schumacher or Suzanne Adelman, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335.

Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 317–6846.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*http://www.dol.gov/ebsa*). In addition, information from HHS on private health insurance for consumers can be found on the CMS Web site (*www.cciio.cms.gov*), and information on health reform can be found at *http://www.HealthCare.gov.*

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the

Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make those provisions applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage of certain specified preventive services without cost sharing. These preventive services include preventive care and screenings for women provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). On August 1, 2011, the Departments amended regulations to cover women's preventive services provided for in HRSA guidelines,[1] and HRSA adopted and released such guidelines, which were based on recommendations of the independent organization, the National Academy of Medicine (formerly Institute of Medicine). The preventive services identified in the HRSA guidelines include all Food and Drug Administration (FDA)-approved contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).[2]

The Departments issued regulations that provide an accommodation for eligible organizations that object on religious grounds to providing coverage for contraceptive services.[3] Under the accommodation, an eligible organization does not have to contract, arrange, pay, or provide a referral for contraceptive coverage. At the same time, the accommodation generally ensures that women enrolled in the health plan established by the eligible organization, like women enrolled in health plans maintained by other employers, receive contraceptive coverage seamlessly—that is, through the same issuers or third party administrators that provide or administer the rest of their health coverage, and without financial, logistical, or administrative obstacles.[4] Minimizing such obstacles is essential to achieving the purpose of the Affordable Care Act's preventive services provision, which seeks to remove barriers to the use of preventive services and to ensure that women receive full and equal health coverage appropriate to their medical needs.

Under the Departments' regulations, an eligible organization may invoke the accommodation by self-certifying its eligibility using a form provided by the Department of Labor, EBSA Form 700, and providing the form to its health insurance issuer (to the extent it has an insured plan) or third party administrator (to the extent it has a self-insured plan).[5] Alternatively, instead of sending the self-certification form to its issuer or third party administrator, the regulations allow an eligible organization to invoke the accommodation by providing certain information to HHS, without using any particular form.[6]

In *Zubik* v. *Burwell,* 136 S. Ct. 1557 (2016), the Supreme Court considered claims by a number of employers that, even with the accommodation provided in the regulations, the contraceptive-coverage requirement violates the Religious Freedom Restoration Act of 1993 (RFRA). Following oral argument, the Court requested supplemental briefing from the parties. The Court's order noted that under the existing regulations, an objecting employer with an insured plan that seeks to invoke the accommodation by contacting its issuer must use a form of notice provided by the government.[7] The Court directed the parties to file supplemental briefs addressing ''whether contraceptive coverage could be provided to [the objecting employers'] employees, through [the employers'] insurance companies, without any such notice.'' [8] After consideration of the supplemental briefing, the Supreme Court vacated the judgments of the courts below and remanded *Zubik* and several other cases raising parallel RFRA challenges to the accommodation. 136 S. Ct. at 1560–1561. The Court emphasized that it ''expresse[d] no view on the merits of the cases'' and, in particular, that it did not ''decide whether [the employers'] religious exercise has been substantially burdened, whether the Government has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest.'' *Id.* at 1560. The Court, however, stated that in light of what it viewed as ''the substantial clarification and refinement in the positions of the parties'' in their supplemental briefs, the parties ''should be afforded an opportunity to arrive at an approach going forward that accommodates [the objecting employers'] religious exercise while at the same time ensuring that women covered by [the employers'] health plans 'receive full and equal health coverage, including contraceptive coverage.'" *Id.* (citation omitted).

As the government explained in its briefs in *Zubik,* the Departments continue to believe that the existing accommodation regulations are consistent with RFRA for two independent reasons. First, as eight of the nine courts of appeals to consider the issue have held, the accommodation does not substantially burden objecting employers' exercise of religion. Second, as some of those courts have also held, the accommodation is the least restrictive means of furthering the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage. Nevertheless, the Departments also are committed to respecting the beliefs of religious employers that object to providing contraceptive coverage, and the Departments have consistently sought to accommodate religious objections to the contraceptive-coverage requirement even where not required to do so by RFRA. Consistent with that approach, the Departments are issuing this Request for Information (RFI) to determine, as contemplated by the Supreme Court's opinion in *Zubik,* whether modifications to the existing accommodation procedure could resolve the objections asserted by the plaintiffs in the pending RFRA cases while still ensuring that the affected women seamlessly receive full and equal health coverage, including contraceptive coverage.

The Departments are using the RFI procedure because the issues addressed in the supplemental briefing in *Zubik* affect a wide variety of stakeholders,

[1] 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, 45 CFR 147.130.

[2] The HRSA guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

[3] 26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A, 45 CFR 147.131.

[4] An accommodation is also available with respect to student health insurance coverage arranged by eligible organizations that are institutions of higher education. 45 CFR 147.131(f). For ease of use, this RFI refers only to ''employers'' with religious objections to the contraceptive-coverage requirement, but references to employers with respect to insured group health plans should also be considered to include institutions of higher education that are eligible organizations with respect to student health insurance coverage.

[5] The EBSA form 700 is available at: *https://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf*

[6] A model notice to HHS that eligible organizations may, but are not required to, use is available at: *http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Prevention.*

[7] *Zubik* v. *Burwell,* Nos. 14–1418 et al., 2016 WL 1203818, at *2 (Mar. 29, 2016).

[8] *Id.*

including many who are not parties to the cases that were before the Supreme Court. Other employers also have brought RFRA challenges to the accommodation, and their views may differ from the views held by the employers in *Zubik* and the consolidated cases. In addition, any change to the accommodation could have implications for the rights and obligations of issuers, third party administrators, and women enrolled in health plans established by objecting employers. RFIs are commonly used to solicit public comments on potential rulemaking in a transparent and open way. Information gathered through this RFI will be used to determine whether changes to the current regulations should be made and, if so, to inform the nature of those changes. The Departments welcome comments from all stakeholders. A principal purpose of this RFI is to determine whether there are modifications to the accommodation that would be available under current law and that could resolve the RFRA claims raised by organizations that object to the existing accommodation on religious grounds. The Departments invite all such organizations to submit comments, and request that their submissions include specific responses to the questions posed below.[9]

II. Solicitation of Comments

A. Notification to Issuers Without Self-Certification

In its request for supplemental briefing in *Zubik,* the Supreme Court asked the parties to address whether and how ''contraceptive coverage may be obtained by [objecting employers'] employees through [the employers'] insurance companies, but in a way that does not require any involvement of [the employers] beyond their own decision to provide health insurance without contraceptive coverage to their employees.'' [10] In particular, the Court posited ''a situation in which [objecting employers] would contract to provide health insurance for their employees, and in the course of obtaining such insurance, inform their insurance company that they do not want their health plan to include contraceptive coverage of the type to which they object on religious grounds. [The employers] would have no legal obligation to provide such contraceptive coverage, would not pay for such coverage, and would not be required to submit any separate notice to their insurer, to the Federal government, or to their employees. At the same time, [the employers'] insurance compan[ies]—aware that [the employers] are not providing certain contraceptive coverage on religious grounds—would separately notify [the employers'] employees that the insurance company will provide cost-free contraceptive coverage, and that such coverage is not paid for by [the employers] and is not provided through [the employers'] health plan[s].'' [11]

In response, the government explained:

> For employers with insured plans, the Court described an arrangement very similar to the existing accommodation. The accommodation already relieves [employers with religious objections] of any obligation to provide contraceptive coverage and instead requires insurers to provide coverage separately. The only difference is the way the accommodation is invoked. Currently, an employer that chooses to opt out by notifying its insurer (rather than HHS) must use a written form self-certifying its religious objection and eligibility for the accommodation. The Court's order posited an alternative procedure in which the employer could opt out by asking an insurer for a policy that excluded contraceptives to which it objects. That request would not need to take any particular form, but the employer and the insurer would be in the same position as after a self-certification: The employer's obligation to provide contraceptive coverage would be extinguished, and the insurer would instead be required to provide the coverage separately.'' Gov't Supp. Brief 2 (citation omitted); see *id.* 3–7.[12]

The government explained that because ''[i]nsurers have an independent statutory obligation to provide contraceptive coverage,'' ''the accommodation for employers with insured plans could be modified to operate in the manner posited in the Court's order while still ensuring that the affected women receive contraceptive coverage seamlessly, together with the rest of their health coverage.'' *Id.* at 14–15. The government also noted, however, that the current requirement of a written self-certification plays an important role in effectuating the accommodation, and therefore cautioned that such a modification could ''impose real costs on the parties whose rights and duties are affected—including objecting employers.'' *Id.* at 14; see *id.* at 8–11 (describing the function of the self-certification requirement).

The Departments seek comments from all interested stakeholders, including all objecting employers, on the procedure for invoking the accommodation described above, including with respect to the following:

1. The Departments ask objecting organizations with insured plans to indicate whether the alternative procedure described above would resolve their RFRA objections to the accommodation. If it would not resolve a particular organization's RFRA objection, the Departments ask the organization to indicate whether its RFRA objection could be resolved by any procedure(s) or system(s) in which the organization's issuer provides contraceptive coverage to the women enrolled in the organization's health plan, and, if so, describe the procedure(s) or system(s) with specificity.

2. The Supreme Court's supplemental briefing order appears to contemplate that, in requesting insurance coverage that excludes contraceptive coverage, an employer would inform its issuer that it objects to providing contraceptive coverage ''on religious grounds.'' [13] The Departments ask objecting organizations to indicate whether they would have any RFRA objection to informing their issuers that they object to providing contraceptive coverage ''on religious grounds,'' or to a further requirement that the request by an eligible organization [14] to its issuer be made in writing, or to a further requirement that the request be made via a particular form.

3. The government's supplemental brief explained that eliminating the written notification requirement in the existing accommodation could impose additional burdens on objecting employers, issuers, and regulators. Gov't Supp. Br. 8–10, 14–15. The Departments seek comment on the extent of those burdens and what steps could be taken

[9] Consistent with the Supreme Court's decision in *Zubik,* the Departments seek to determine whether changes to the existing accommodation could resolve the pending RFRA claims brought by objecting employers. The Supreme Court separately specified that, while the RFRA litigation remains pending, ''the Government may not impose taxes or penalties on [the plaintiffs] for failure to provide the . . . notice'' required under the existing accommodation regulations. *Zubik,* 136 S. Ct. at 1561. At the same time, the Court also emphasized that ''[n]othing in [its] opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by [plaintiffs'] health plans 'obtain, without cost, the full range of FDA approved contraceptives.''' *Id.* at 1560–1561 (quoting *Wheaton College* v. *Burwell,* 134 S. Ct. 2806, 2807 (2014)). As such, those interim matters are not within the scope of this RFI.

[10] *Zubik,* 2016 WL 1203818, at *2.

[11] *Id.*

[12] The government's supplemental brief is available at *https://www.justice.gov/osg/brief/zubik-v-burwell-0.* The government's supplemental reply brief is available at *https://www.justice.gov/osg/brief/zubik-v-burwell-1.*

[13] *Zubik,* 2016 WL 1203818, at *2.

[14] An eligible organization, which may seek the accommodation based on its sincerely held religious objection to providing contraceptive coverage, is defined at 26 CFR 54.9815–2713A(a), 29 CFR 2590.715–2713A(a), and 45 CFR 147.131(b).

to mitigate them. The Departments ask health insurance issuers, as well as other commenters, to indicate whether it is feasible for issuers to implement the accommodation without the written notification requirement.

4. What impact would the alternative procedure described above have on the ability of women enrolled in group health plans established by objecting employers to receive seamless coverage for contraceptive services?

B. Other Approaches With Respect to Insured Plans Described in the Supplemental Briefing

In their supplemental brief, the plaintiffs in *Zubik* and the consolidated cases proposed additional modifications to the existing accommodation for insured plans, beyond those described in the Supreme Court's supplemental briefing order and discussed above. As in the alternative described above, the *Zubik* plaintiffs proposed that when an eligible employer with an insured plan requests insurance coverage that excludes contraceptive coverage to which the employer objects on religious grounds, the employer's issuer should be required to provide the required coverage separately. However, the *Zubik* plaintiffs further proposed that the separate coverage provided by the issuer should differ from the separate coverage required under the existing accommodation in two respects. First, the *Zubik* plaintiffs proposed that the issuer be required to offer women the opportunity to enroll in contraceptive-only insurance policies, rather than the issuer providing separate direct payments for contraceptive services. Second, the *Zubik* plaintiffs proposed that the affected women should be required to take affirmative steps to enroll in those contraceptive-only policies, rather than being automatically eligible for payments by the issuer for contraceptive services. Pet. Supp. Br. 3–12.[15]

The Departments seek comments on this approach, including with respect to the following:

1. The Departments ask objecting organizations with insured plans to indicate whether this alternative procedure would resolve their RFRA objections to the accommodation.

2. What impact would this approach have on the ability of women enrolled in group health plans established by objecting employers to receive seamless coverage for contraceptive services?

3. Is this approach feasible for health insurance issuers?

4. Relying on the record developed in the prior rulemaking proceedings, the government's supplemental reply brief in *Zubik* explained that contraceptive-only insurance policies would be inconsistent with state laws regulating insurance and that an affirmative enrollment requirement would impose a barrier to access to preventive services. Gov't Supp. Reply Br. 3–6. The Departments seek further comment on those issues in this RFI.

5. Are there alternative procedure(s) or systems (without relying on contraceptive-only policies or imposing an affirmative enrollment requirement) that would resolve objecting organizations' RFRA objection to the accommodation? If so, please describe the procedure(s) or system(s) with specificity.

C. Self-Insured Plans

The Supreme Court's supplemental briefing order in *Zubik* addressed only employers with "insured plans." [16] In its supplemental brief, the government described the operation of the accommodation for self-insured plans and explained that an alternative process like the one the Court posited for insured plans could not work for the many employers with self-insured plans:

> If an employer has a self-insured plan, the statutory obligation to provide contraceptive coverage falls only on the plan—there is no insurer with a preexisting duty to provide coverage. Accordingly, to relieve self-insured employers of any obligation to provide contraceptive coverage while still ensuring that the affected women receive coverage without the employer's involvement, the accommodation establishes a mechanism for the government to designate the employer's TPA as a 'plan administrator' responsible for separately providing the required coverage under [ERISA]. That designation is made by the government, not the employer, and the employer does not fund, control, or have any other involvement with the separate portion of the ERISA plan administered by the TPA.
>
> The government's designation of the TPA must be reflected in a written plan instrument. To satisfy that requirement, the accommodation relies on either (1) a written designation sent by the government to the TPA, which requires the government to know the TPA's identity, or (2) the self-certification form, which the regulations treat as a plan instrument in which the government designates the TPA as a plan administrator. There is no mechanism for requiring TPAs to provide separate contraceptive coverage without a plan instrument; self-insured employers could not opt out of the contraceptive-coverage requirement by simply informing their TPAs that they do not want to provide coverage for contraceptives. Gov't Supp. Br. 16–17 (citations omitted).

The *Zubik* plaintiffs also stated that an arrangement like the one posited in the Supreme Court's briefing order for insured plans could not work for self-insured plans. See Pet. Supp. Br. 16–17.

Although the Departments have not identified any viable alternative to the existing accommodation for self-insured plans, they seek comment on any possible modifications to the accommodation for self-insured plans, including self-insured church plans that would resolve objecting organizations' RFRA objections while still providing seamless access to coverage, including with respect to the following:

1. Are any reasonable alternative means available under existing law by which the Departments could ensure that women enrolled in self-insured plans maintained by objecting employers receive separate contraceptive coverage that is not contracted, arranged, paid, or referred for by the objecting organization but that is provided through the same third party administrators that administer the rest of their health benefits?

2. The Departments ask objecting organizations with self-insured plans to indicate whether their RFRA objections to the existing accommodation could be resolved by any alternative procedure or system in which the objecting organization's third party administrator provides contraceptive coverage to the women enrolled in the organization's health plan, and, if so, to describe the procedure(s) or system(s) with specificity.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

[15] Petitioners' supplemental brief is available at *http://www.scotusblog.com/wp-content/uploads/2016/04/Non-profits-response-to-Zubik-order-4-12-16.pdf*. Petitioners' supplemental reply brief is available at *http://www.scotusblog.com/wp-content/uploads/2016/04/Zubik-order-non-profits-reply-brief-4-20-161.pdf*.

[16] *Zubik*, 2016 WL 1203818, at *2.

Signed at Washington, DC, this 18th day of July, 2016.

Victoria A. Judson,

Associate Chief Counsel (Tax Exempt and Government Entities), Internal Revenue Service, Department of the Treasury.

Signed this 18th day of July, 2016.

Robert J. Neis,

Benefits Tax Counsel, Department of the Treasury.

Signed this 18th day of July, 2016.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration Department of Labor.

Dated: July 14, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: July 15, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–17242 Filed 7–21–16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R01–OAR–2015–0306; A–1–FRL–9949–31–Region 1]

Air Plan Approval; Rhode Island; Correction, Administrative and Miscellaneous Revisions

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Rhode Island. This SIP revision includes fifteen revised Rhode Island Air Pollution Control Regulations. These regulations have been previously approved into the Rhode Island SIP and the revisions to these regulations are mainly administrative in nature, but also include technical corrections and a few substantive changes to several of the rules. In addition, EPA is proposing a correction to the Rhode Island SIP to remove Rhode Island's odor regulation because it was previously erroneously approved into the SIP. The intended effect of this action is to propose to approve Rhode Island's fifteen revised regulations into the Rhode Island SIP and correct the Rhode Island SIP by removing Rhode Island's odor regulation. This action is being taken in accordance with the Clean Air Act.

DATES: Written comments must be received on or before August 22, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R01–OAR–2015–0306 at *http://www.regulations.gov,* or via email to *mcdonnell.ida@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the ''For Further Information Contact'' section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lancey, Air Permits, Toxics and Indoor Programs Unit, Office of Ecosystem Protection, 5 Post Office Square—Suite 100, (Mail code OEP05–2), Boston, MA 02109–3912, telephone 617–918–1656, fax 617–918–0656, email *lancey.susan@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Rules and Regulations section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of the rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the Rules and Regulations section of this **Federal Register**.

Dated: July 5, 2016.

H. Curtis Spalding,

Regional Administrator, EPA New England.

[FR Doc. 2016–17183 Filed 7–21–16; 8:45 am]

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